CHEMICAL SAFETY REPORT

Substance Name: diammonium hexachloroplatinate
EC Number: 240-973-0
CAS Number: 16919-58-7
Registrant's Identity:

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Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

The risk management measures for all Exposure Scenarios are described in Chapters 9 and 10 of part B of this CSR.

The above part A element applies to: CSR (all uses)

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

Each EU manufacturer and importer, having decided to mandate the Lead Registrant to submit this CSR on his behalf, endorses the declaration that he implements those risk management measures described in Part B, Chapter 9+10 of this document, that are relevant to his manufacture or import and own uses. Registrants that submit their own Part A are excluded from the afore-mentioned endorsement.

The above part A element applies to: CSR (all uses)

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

Each EU manufacturer, importer and Only Representative having decided to mandate the Lead Registrant to submit this CSR on his behalf endorses the declaration that he communicates to distributors and the downstream users those risk management measures that are relevant for their uses as described in Part B, Section 9+10 of this document. Registrants that submit their own Part A are excluded from the afore-mentioned endorsement.

The above part A element applies to: CSR (all uses)

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

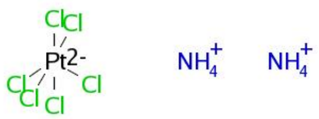
1.1. Name and other identifiers of the substance

The substance diammonium hexachloroplatinate is a mono-constituent substance (inorganic) having the following characteristics and physical-chemical properties (see the IUCLID dataset for further details).

Table 1.1. Substance identity

EC number:	240-973-0
EC name:	diammonium hexachloroplatinate
CAS number (EC inventory):	16919-58-7
CAS number:	16919-58-7
IUPAC name:	diammonium hexachloroplatinate(2-)
Synonyms:	Synonyms Platinate(2-), hexachloro-, diammonium, (OC-6-11)- Platinate(2-), hexachloro-, diammonium, (OC-6-11)-
Molecular formula:	Cl6Pt.2H4N
Molecular weight range:	443.879

Figure 1.1. 16919-58-7-V2.jpeg



1.2. Composition of the substance

Overall information on composition:

Composition	Related composition(s)
Diammonium hexachloroplatinate - Registration boundary conditions (boundary composition of the substance)	
Diammonium hexachloroplatinate (legal entity composition of the substance)	

Name: Diammonium hexachloroplatinate - Registration boundary conditions

(boundary composition of the substance)

State/form: solid: particulate/powder
Degree of purity: >=99.7 - <=100 % (w/w)
Description: Mono-constituent substance

Table 1.2. Constituents (Diammonium hexachloroplatinate - Registration boundary conditions)

Constituent	Typical concentration	Concentration range	Remarks
diammonium hexachloroplatinate EC no.: 240-973-0	99.7 % (w/w)	>=99.7 - <=100 % (w/w)	

Table 1.3. Impurities (Diammonium hexachloroplatinate - Registration boundary conditions)

Constituent	Typical concentration	Concentration range	Remarks
sodium EC no.: 231-132-9	<0.2 % (w/w)	>=0 - <=0.2 % (w/w)	
Impurities EC no.:	<0.1 % (w/w)	>=0 - <=0.1 % (w/w)	Several minor (especially metallic, e.g. Ag, Au, Cu, Ir, Pb, Pd, Rh, Ru) impurities which do not affect the classification of the substance because of their non-hazardous nature or because they do not exceed the classification cut-off limits in the substance

Name: Diammonium hexachloroplatinate

(legal entity composition of the substance)
State/form: solid: particulate/powder
Degree of purity: % (w/w)
Description: Mono-constituent substance

Table 1.4. Constituents (Diammonium hexachloroplatinate)

Constituent	Typical concentration	Concentration range	Remarks
diammonium hexachloroplatinate EC no.: 240-973-0	% (w/w)	% (w/w)	

Table 1.5. Impurities (Diammonium hexachloroplatinate)

Constituent	Typical concentration	Concentration range	Remarks
sodium EC no.: 231-132-9	% (w/w)	% (w/w)	
Impurities EC no.:	% (w/w)	% (w/w)	Several minor (especially metallic, e.g. Ag, Au, Cu, Ir, Pb, Pd, Rh, Ru) impurities which do not affect the classification of the substance because of their non-hazardous nature or because they do not exceed the classification cut-off limits in the substance

Justification for reporting set of similar nanoforms:

Shape
No information available on Shape from IUCLID

Particle size distribution and range
No information available on Particle size distribution and range from IUCLID

Crystallinity
No information available on Crystallinity in IUCLID

Specific surface area
No information available on Specific surface area from IUCLID

Surface functionalisation / treatment
No information available Surface functionalisation / treatment from IUCLID

Justification for reporting set of similar nanoforms:

Shape
No information available on Shape from IUCLID

Particle size distribution and range
No information available on Particle size distribution and range from IUCLID

Crystallinity
No information available on Crystallinity in IUCLID

Specific surface area
No information available on Specific surface area from IUCLID

Surface functionalisation / treatment
No information available Surface functionalisation / treatment from IUCLID

1.3. Information on linked categories

1.4. Physicochemical properties

Table 1.6. Physicochemical properties

Property	Value used for CSA / Discussion	Description of key information
Physical state	**solid at 20°C and 101.3 kPa** The statement on appearance is taken from the test material section of a GLP-compliant, guideline study available as an unpublished report (Tremain & Atwal 2011). The statement from the study is considered to be suitable for use as the key study for this endpoint. Diammonium hexachloroplatinate is an orange powder Supporting information is taken from a reliable peer reviewed handbook (Lide 2008) and so can be considered suitable for use as the key study for this endpoint. At 20ºC and 1013 hPa Diammonium	At 20ºC and 1013 hPa Diammonium hexachloroplatinate is inorganic red orange cubic crystals or an orange powder.

	hexachloroplatinate is inorganic red orange cubic crystals.	
Melting / freezing point	**380°C at 101.3 kPa** The CRC Handbook (Lide, 2008) is a reliable, peer reviewed handbook and so can be considered suitable for use as the key study for this endpoint. The decomposition temperature of Diammonium hexachloroplatinate is 380 °C.	The decomposition temperature of Diammonium hexachloroplatinate is 380 °C.
Relative density	**3.065 at 20°C** The CRC Handbook (Lide, 2008) is a reliable peer reviewed handbook and so can be considered suitable for use as the key study for this endpoint. The density of Diammonium hexachloroplatinate is 3.065 g/cm3.	The density of Diammonium hexachloroplatinate is 3.065 g/cm3.
Granulometry	This is a GLP compliant, guideline study considered suitable for use as the key study for this endpoint. The proportion of Diammonium hexachloroplatinate < 100 µm is 0.4 % (Tremain & Atwal 2011).	In an OECD 110 Granulometry screening Test the proportion of Diammonium hexachloroplatinate <100 µm was 0.4 %.
Water solubility	The CRC Handbook (Lide, 2008) is a reliable peer reviewed handbook and so can be considered reliable and suitable for use as the key study for this endpoint. Diammonium hexachloroplatinate has a solubility of 0.50g/100g H2O at 20°C.	Diammonium hexachloroplatinate has a solubility of 0.50g/100g H2O at 20°C.
Autoflammability / self-ignition temperature	This is a GLP compliant, guideline study considered suitable for use as the key study for this endpoint (Tremain & Atwal 2011). Diammonium hexachloroplatinate showed no signs of self-ignition or self heating over the duration of the test).	Diammonium hexachloroplatinate showed no signs of self-ignition or self-heating over the duration of the test
Flammability	**not classified** This is a GLP compliant, guideline study considered suitable for use as the key study for this endpoint (Tremain & Atwal 2011).	Diammonium hexachloroplatinate is not classified as a flammable solid in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on

	Diammonium hexachloroplatinate is not classified as a flammable solid in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures as it failed to ignite in the preliminary screening test.	Classification, Labelling and Packaging of Substances and Mixtures as the pile failed to ignite in the two minutes the Bunsen flame was applied.
Oxidising properties	**no** The oxidising properties of diammonium hexachloroplatinate are read across from other substances with co-ordinated chloride, in the 4+ oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid). Neither of these substances are oxidising based on GLP-compliant, guideline experimental studies (Tremain & Atwal 2011, Walker & White 2011).There is also supplementary evidence that other metal chlorides are also not oxidizing. For example, other Group VIII transition metals such as cobalt (II) chloride, iron (II), iron(III) and nickel(II) chloride. Copper(I) chloride from the adjacent Group IB is also not classified for oxidizing properties, there is therefore no evidence that any transition metal chloride is an oxidant. Supplementary evidence also comes from the non-transition metal chlorides and there is no evidence from two centuries of industrial and academic experience that these substances are oxidants. On the basis of read-across diammonium hexachloroplatinate is not classified as an oxidising solid.	On the basis of read-across from test results for other substances with co-ordinated chloride, in the 4+ oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid), diammonium hexachloroplatinate is not considered to be oxidising.
Other studies	This is a GLP compliant, guideline study which is considered suitable for use for assessment (Tremain and Atwal 2011). Diammonium hexachloroplatinate is classified as Metal corrosivity category 1 in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures.	Diammonium hexachloroplatinate is classified as Metal corrosivity category 1 in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures.

Data waiving

Information requirement: Boiling point

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is a solid which melts above 300°C [study scientifically not necessary / other information available]

Information requirement: Vapour pressure

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the melting point is above 300°C [study scientifically not necessary / other information available]

Information requirement: Partition coefficient n-octanol/water (log value)

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is inorganic [study technically not feasible]

Information requirement: Surface tension

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because based on structure, surface activity is not expected or cannot be predicted [study scientifically not necessary / other information available] ; the study does not need to be conducted because surface activity is not a desired property of the material [study scientifically not necessary / other information available]

Information requirement: Flash point

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is inorganic [study technically not feasible] ; the study does not need to be conducted because the flash point is only relevant to liquids and low melting point solids [study technically not feasible]

Information requirement: Explosive properties

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties [study scientifically not necessary / other information available]

Discussion of physicochemical properties

Additional information:

Physico-chemical endpoints are completed for this substance based on handbook data, data generated as part of the REACH registration process, relevant data waivers and suitable read across.

Based on the results of an experimental study this substance is classified as Metal corrosivity category 1 (H290).

2. MANUFACTURE AND USES

2.1. Manufacture

Table 2.1. Manufacture

	Manufacture
M-1	**Manufacture of substance (as such)** Further description of manufacturing process: Platinum chloride solution is oxidised with a suitable oxidising agent such as hydrogen peroxide to ensure that all the platinum is present in the +IV oxidation state. Ammonium chloride is then added to precipitate out yellow ammonium hexachloroplatinate. Contributing activity/technique for the environment : **- ERC1: Manufacture of the substance** Contributing activity/technique for the workers : **- Raw material handling (PROC 1 ; PROC 8b ; PROC 9 ; PROC 21 ; PROC 26)** **- Sampling/Evaluation (PROC 15)** **- Wet processing (PROC 1 ; PROC 2 ; PROC 3 ; PROC 4 ; PROC 5)** **- Separating/Filtration (PROC 1 ; PROC 2 ; PROC 3 ; PROC 4)** **- Washing/Drying (PROC 1 ; PROC 2 ; PROC 3 ; PROC 4)** **- Calcination (PROC 1)** **- Milling/Grinding/Sieving (PROC 1)** **- Packaging/Filling (PROC 1 ; PROC 8b ; PROC 9 ; PROC 21)** **- Cleaning and maintenance (PROC 8a ; PROC 26)** Tonnage of substance for that use: tonnes/year Related assessment:

2.2. Identified uses

No information available on identified uses.

Table 2.2. Uses at industrial sites

	Uses at industrial sites
IW-1	**Use as an intermediate** Further description of the use: Contributing activity/technique for the environment : **- ERC6a: Use of intermediate** Contributing activity/technique for the workers : **- Handling of medium/high dusty materials (PROC 26)** **- Handling of low dusty material (PROC 26)** **- Handling of solutions and reaction (PROC 3 ; PROC 4 ; PROC 5 ; PROC 8b ; PROC 9 ; PROC 15)** **- Fully contained process (PROC 1)** **- Reaction process (PROC 22)** **- Wet powder production (PROC 27a)** **- Hot powder production (PROC 27b)** **- Wet cleaning (PROC 8a)** **- Vacuum cleaning (PROC 26)** **Sector of end use:** SU 9: Manufacture of fine chemicals ; SU 14: Manufacture of basic metals, including alloys **Technical function of the substance:** intermediate (precursor)

	Tonnage of substance for that use: tonnes/year Substance supplied to that use: Subsequent service life relevant for that use: no

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Substance: Diammonium hexachloroplatinate (harmonised)
Implementation: EU
Related composition: Boundary Composition

Table 3.1. Classification and labelling according to CLP / GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement	Reason for no classification
Explosives:			data conclusive but not sufficient for classification
Desensitised explosives:			data lacking
Flammable gases and chemically unstable gases:			data conclusive but not sufficient for classification
Aerosols:			data conclusive but not sufficient for classification
Chemicals under Pressure:			hazard class not assessed
Oxidising gases:			data conclusive but not sufficient for classification
Gases under pressure:			data conclusive but not sufficient for classification
Flammable liquids:			data conclusive but not sufficient for classification
Flammable solids:			data conclusive but not sufficient for classification
Self-reactive substances and mixtures:			data conclusive but not sufficient for classification
Pyrophoric liquids:			data conclusive but not sufficient for classification
Pyrophoric solids:			data conclusive but not sufficient for classification
Self-heating substances and mixtures:			data conclusive but not sufficient for classification
Substances and mixtures which in contact with water emit flammable gases:			data conclusive but not sufficient for classification
Oxidising liquids:			data conclusive but not sufficient for classification
Oxidising solids:			data conclusive but not sufficient for classification

Organic peroxides:			data conclusive but not sufficient for classification
Corrosive to metals:	Met. Corr. 1	H290: May be corrosive to metals.	

Table 3.2. Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:	Acute Tox. 3	H301: Toxic if swallowed.	
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:			data lacking
Serious damage / eye irritation:	Eye Damage 1	H318: Causes serious eye damage.	
Respiratory sensitisation:	Resp. Sens. 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Skin sensitisation:	Skin Sens. 1	H317: May cause an allergic skin reaction.	
Aspiration hazard:			data lacking
Reproductive Toxicity:			data lacking
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:			data lacking
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:			data lacking
Specific target organ toxicity – repeated exposure:			data lacking

Table 3.3. Classification and labelling according to CLP / GHS for environmental hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):			data lacking
Hazards to the aquatic environment (chronic/long-term):			data lacking
M-Factor acute:			
M-Factor chronic:			

Hazardous to the ozone layer:			data lacking

Labelling

Signal word: Danger

Hazard pictogram:

GHS05: corrosion

GHS06: skull and crossbones

GHS08: health hazard

Hazard statements:

H290: May be corrosive to metals.

H301: Toxic if swallowed.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements:

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P103: Read carefully and follow all instructions.

P234: Keep only in original packaging.

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash ... thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

P272: Contaminated work clothing should not be allowed out of the workplace.

P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P284: [In case of inadequate ventilation] wear respiratory protection.

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor/…

P302+P352: IF ON SKIN: Wash with plenty of water/…

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.
P310: Immediately call a POISON CENTER/doctor/…
P321: Specific treatment (see ... on this label).
P330: Rinse mouth.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor/…
P362+P364: Take off contaminated clothing and wash it before reuse.
P390: Absorb spillage to prevent material damage.
P405: Store locked up.
P406: Store in a corrosion resistant/... container with a resistant inner liner.
P501: Dispose of contents/container to ...

Substance: Diammonium hexachloroplatinate
Implementation: EU
Remarks:

Self-classification - using the harmonised Annex VI classification and further available data

Related composition: Boundary Composition

Table 3.4. Classification and labelling according to CLP / GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement	Reason for no classification
Explosives:			data conclusive but not sufficient for classification
Desensitised explosives:			data conclusive but not sufficient for classification
Flammable gases and chemically unstable gases:			data conclusive but not sufficient for classification
Aerosols:			data conclusive but not sufficient for classification
Chemicals under Pressure:			hazard class not assessed
Oxidising gases:			data conclusive but not sufficient for classification
Gases under pressure:			data conclusive but not sufficient for classification
Flammable liquids:			data conclusive but not sufficient for classification
Flammable solids:			data conclusive but not sufficient for classification
Self-reactive substances and mixtures:			data conclusive but not sufficient for classification
Pyrophoric liquids:			data conclusive but not sufficient for classification
Pyrophoric solids:			data conclusive but not sufficient for classification
Self-heating			data conclusive but not

substances and mixtures:			sufficient for classification
Substances and mixtures which in contact with water emit flammable gases:			data conclusive but not sufficient for classification
Oxidising liquids:			data conclusive but not sufficient for classification
Oxidising solids:			data conclusive but not sufficient for classification
Organic peroxides:			data conclusive but not sufficient for classification
Corrosive to metals:	Met. Corr. 1	H290: May be corrosive to metals.	

Table 3.5. Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:	Acute Tox. 3	H301: Toxic if swallowed.	
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:			data conclusive but not sufficient for classification
Serious damage / eye irritation:	Eye Damage 1	H318: Causes serious eye damage.	
Respiratory sensitisation:	Resp. Sens. 1A	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Skin sensitisation:	Skin Sens. 1B	H317: May cause an allergic skin reaction.	
Aspiration hazard:			data lacking
Reproductive Toxicity:			data conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:			data conclusive but not sufficient for classification
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:			data conclusive but not sufficient for classification
Specific target organ toxicity – repeated exposure:	STOT Rep. Exp. 1 Affected organs: kidney	H372: Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of	

		exposure cause the hazard>.	

Table 3.6. Classification and labelling according to CLP / GHS for environmental hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):	Aquatic Acute 1	H400: Very toxic to aquatic life.	
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects.	
M-Factor acute: 1			
M-Factor chronic: 1			
Hazardous to the ozone layer:			data conclusive but not sufficient for classification

Labelling

Signal word: Danger

Hazard pictogram:

GHS05: corrosion

GHS06: skull and crossbones

GHS08: health hazard

GHS09: environment

Hazard statements:

H290: May be corrosive to metals.

H301: Toxic if swallowed.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H372: Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P103: Read carefully and follow all instructions.

P234: Keep only in original packaging.

P260: Do not breathe dust/fume/gas/mist/vapours/spray.

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash ... thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

P272: Contaminated work clothing should not be allowed out of the workplace.

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P284: [In case of inadequate ventilation] wear respiratory protection.

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor/…

P302+P352: IF ON SKIN: Wash with plenty of water/…

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310: Immediately call a POISON CENTER/doctor/…

P314: Get medical advice/attention if you feel unwell.

P321: Specific treatment (see ... on this label).

P330: Rinse mouth.

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor/…

P362+P364: Take off contaminated clothing and wash it before reuse.

P390: Absorb spillage to prevent material damage.

P391: Collect spillage.

P405: Store locked up.

P406: Store in a corrosion resistant/... container with a resistant inner liner.

P501: Dispose of contents/container to ...

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

Key Information:

The log Kd for water is 3.27 (stdev 0.34) and the average Kd is 1862. The log Kd for soil is 1.57 (stdev 0.46) and the average Kd is 37.2.

Additional information:

Two high quality studies have determined the partitioning of platinum between river water and suspended particulate matter. Both studies showed relatively consistent results for experiments performed in freshwaters, and similar partitioning was also observed in both estuarine and marine water in the key study (Turner et al., 2006; Cobelo-Garcia et al., 2008). A high quality study of the partitioning of platinum to two soils and one sediment provides information relevant to the soil compartment (Sako et al., 2009).

Hydrolysis and biodegradation potential have not been assessed for this substance as these endpoints are not relevant for inorganics.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

No relevant information available.

Data waiving

Information requirement: Hydrolysis

Reason: study scientifically not necessary / other information available

Justification: see ‘Remark’ - In accordance with REACH Annex XI Section 1 testing does not appear to be scientifically necessary because this method is used on organic substances to measure the decomposition or degradation of a chemical reacting with water. For inorganics this type of method is not appropriate.

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available.

4.1.1.2.2. Phototransformation in water

No relevant information available.

4.1.1.2.3. Phototransformation in soil

No relevant information available.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

No relevant information available.

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is inorganic [study technically not feasible]

4.1.2.1.2. Simulation tests (water and sediments)

No relevant information available.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

No relevant information available.

4.1.2.2. Biodegradation in soil

No relevant information available.

4.1.3. Summary and discussion of degradation

4.2. Environmental distribution

4.2.1. Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

Table 4.1. Studies on adsorption/desorption

Method	Results	Remarks
adsorption / desorption, other - Determination of sediment Kd values batch equilibrium method Laboratory study, no guideline followed	Adsorption coefficient: log Kd: 3.27 at 23°C (Mean for all salinities, standard deviation 0.34) log Kd: 3.45 at 23°C (Mean for freshwaters, standard deviation 0.24) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) key study experimental study **Test material** Platinum (IV), (full information in **Annex II**). **Reference** **Cobelo-Garcia A, Turner A, Millward G. 2008**
adsorption / desorption, other - Determination of sediment Kd values	Adsorption coefficient: log Kd: 3.27 at 23°C (Mean for all salinities, standard deviation 0.34) log Kd: 3.45 at 23°C (Mean for freshwaters, standard deviation 0.24) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Platinum (IV), (full information in **Annex II**).

		Reference
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH For risk assessment of metals it is not always possible to differentiate between the particular metal substances when conducting environmental monitoring and therefore exposure assessment for platinum (IV) substances is conducted based on total emissions of platinum. Multiple Kd values for each platinum substance are therefore not relevant for risk assessment and Kd values for platinum (IV) are more appropriate. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Platinum (IV) Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For risk assessment purposes, total measured platinum concentrations in the environment are used in order to assess environmental exposure. The risk assessment conducted does not differentiate between platinum (IV) substances but covers all emissions of platinum (IV) substances from a site. As platinum emissions are assessed together, Kd values for platinum (IV) and not for individual platinum substances are relevant.		
adsorption / desorption, other - Determination of sediment Kd values batch equilibrium method Laboratory study, no guideline followed	Adsorption coefficient: log Kd: >3.2 - <3.6 at 20°C (Dependent on treatment of the sediment material.) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) supporting study experimental study **Test material** Pt(IV), Form: gas under pressure: refrigerated liquefied gas (full information in **Annex II**). **Reference** **Turner A, Crussell M, Millward G, Cobelo-Garcia A, Fisher A 2006**
adsorption / desorption, other - Determination of sediment Kd values	Adsorption coefficient: log Kd: >3.2 - <3.6 at 20°C (Dependent on treatment of the sediment material.) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Pt(IV), Form: gas under pressure: refrigerated liquefied gas (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH For risk assessment of metals it is not always possible to differentiate between the particular metal substances when conducting environmental monitoring and therefore exposure assessment for platinum (IV) substances is conducted based on total emissions of platinum. Multiple Kd values for each platinum substance are therefore not relevant for risk assessment and Kd values for platinum (IV) are more appropriate. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Platinum (IV) Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For risk assessment purposes, total		

measured platinum concentrations in the environment are used in order to assess environmental exposure. The risk assessment conducted does not differentiate between platinum (IV) substances but covers all emissions of platinum (IV) substances from a site. As platinum emissions are assessed together, Kd values for platinum (IV) and not for individual platinum substances are relevant.		
adsorption / desorption, other - Determination of soil Kd values batch equilibrium method Laboratory study, no guideline followed	Adsorption coefficient: log Kd: 1.57 at 25°C (Overall mean, standard deviation 0.46) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) supporting study experimental study **Test material** Platinum (IV), (full information in **Annex II**). **Reference** **Sako A, Lopes L, Roychoudhury A 2009**
adsorption / desorption, other - Determination of soil Kd values	Adsorption coefficient: log Kd: 1.57 at 25°C (Overall mean, standard deviation 0.46) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Platinum (IV), (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH For risk assessment of metals it is not always possible to differentiate between the particular metal substances when conducting environmental monitoring and therefore exposure assessment for platinum (IV) substances is conducted based on total emissions of platinum. Multiple Kd values for each platinum substance are therefore not relevant for risk assessment and Kd values for platinum (IV) are more appropriate. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Platinum (IV) Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For risk assessment purposes, total measured platinum concentrations in the environment are used in order to assess environmental exposure. The risk assessment conducted does not differentiate between platinum (IV) substances but covers all emissions of platinum (IV) substances from a site. As platinum emissions are assessed together, Kd values for platinum (IV) and not for individual platinum substances are relevant.		

Discussion

The following information is taken into account for any environmental exposure assessment:

Key Information:

The log Kd for water is 3.27 (stdev 0.34) and the average Kd is 1862. The log Kd for soil is 1.57 (stdev 0.46) and the average Kd is 37.2.

Value used for CSA:
Koc at 20°C:

Additional information:

Two high quality studies have determined the partitioning of platinum between river water and suspended particulate matter. Both studies showed relatively consistent results for experiments performed in freshwaters, and similar partitioning was also observed in both estuarine and marine water in the key study (Turner et al., 2006; Cobelo-Garcia et al., 2008). A high quality study of the partitioning of platinum to two soils and one sediment provides information relevant to the soil compartment (Sako et al., 2009).

Average partition coefficients have been derived in cases where multiple partition coefficients are available for the same type of system (e.g. partitioning to suspended particulate matter in surface waters). The average values have been derived by calculating the log values of the individual partition coefficients (Kd). Following log transformation the mean and standard deviation are calculated to define an "average" partition coefficient and its associated standard deviation, assuming a log-normal distribution of Kd values. The log Kd for water is 3.27 (stdev 0.34) and the average Kd is 1862. The log Kd for soil is 1.57 (stdev 0.46) and the average Kd is 37.2.

4.2.2. Volatilisation

No relevant information available.

4.2.3. Distribution modelling

No relevant information available.

4.2.4. Summary and discussion of environmental distribution

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

No relevant information available.

4.3.2. Terrestrial bioaccumulation

No relevant information available.

4.3.3. Summary and discussion of bioaccumulation

4.4. Secondary poisoning

Based on the available information the bioaccumulation potential cannot be judged (see CSR chapter 7.5 "PNEC derivation and other hazard conclusions").

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1. Non-human information

No relevant information available.

5.1.2. Human information

No relevant information available.

5.1.3. Summary and discussion of toxicokinetics

The following information is taken into account for any hazard / risk assessment:

Key Information:

Diammonium hexachloroplatinate is likely to be poorly absorbed after administration by the oral route; what small proportion of the substance is taken up is likely to be rapidly excreted. Based on experimental rat data on a related soluble platinum salt, an absorption figure of 0.5% is proposed.

Although availability by the inhalation route is anticipated to be low, inhalation absorption is likely extensive based on its water soluble nature and relatively-low molecular weight, as well as limited experimental data. Based on ECHA guidance, a conservative assumption of 100% inhalation absorption is proposed.

A high dermal bioavailability is unlikely, notably based on its high water solubility as well as experimental dermal penetration data (human in vitro studies) for a closely-related surrogate. However, the potential of diammonium hexachloroplatinate to disrupt skin barrier function, facilitating increased dermal penetration, cannot be excluded, especially considering its known corrosivity to metals and to the eyes of rabbits. A value of 20% absorption is proposed.

Once absorbed, distribution and excretion are expected to be rapid, with little or no bioaccumulation occurring, due to the water soluble nature. The potential for bioaccumulation of certain other metals and ions is recognised.

Value used for CSA:
Bioaccumulation potential: low bioaccumulation potential
Absorption rate - oral (%): 0.5
Absorption rate - dermal (%): 20
Absorption rate - inhalation (%): 100

Additional information:

Absorption

Limited data indicate that absorption of soluble Pt compounds is very low following oral exposure. Seventy-one fasted male rats were administered a dose of radiolabelled191Pt (as $PtCl_4$) by oral gavage, to provide 25 µCi of radiation. Routes of excretion, levels of whole-body retention and organ distribution were determined. Less than 0.5% of the orally-administered dose was absorbed (Moore et al., 1975b,c). Similarly, mice given a single gavage administration of radiolabelled Pt(SO4)2 were found to have absorbed only a very small fraction of the dose (Lown et al., 1980). [The authors of this study stated that, while they did not quantify the distribution of the radiolabel, their findings were consistent with those of Moore et al.].

Absorption of platinum from the normal diet was estimated by measuring the levels of platinum in various foods (from a hypothetical diet) and comparing to the concentration of platinum in the urine of 21 individuals. From this the investigators estimated that 42-60% of the dietary platinum was absorbed. US EPA reports the authors of this study as having presented the hypothesis that the approximately 50-fold difference between this estimate and the measured oral absorption in rodents may be a reflection of the greater bioavailability of dietary sources of platinum. Further, this estimate of absorption is based on dietary estimates from a 'hypothetical diet' and that more reliable conclusions on absorption would require measurements from subjects receiving diets with known platinum concentrations (US EPA, 2009). Also, differences between the rat and human absorption figures are likely an artefact of differences in the exposures – absolute dietary Pt content is very low compared to the gavage (bolus) doses administered to the rats, and so it follows that a higher percentage of the lower dose is absorbed and was detected. Moreover, using the lowest oral absorption figure (in this case, 0.5%) results in the most health precautionary DNELs (when extrapolating from an oral exposure to both inhalation and dermal long-term systemic values). Further, ECHA guidance is clear that the preferred approach is to undertake route-to-route extrapolation within one species as the first step. Thus, when deriving DNEL values from experimental studies in the rat, it is most appropriate to use the figures obtained in the toxicokinetic study in rats. Consequently, a figure of 0.5% oral absorption has been taken forward for use in subsequent risk and exposure assessments.

Laboratory studies provide only very limited insights into the extent of absorption of platinum compounds following inhalation. When two volunteers inhaled mainly diammonium hexachloroplatinate at calculated mean air concentrations of 1.7 and 0.15 µg Pt/m3, respectively, urinary Pt concentrations peaked (15-100-fold increases were seen) about 10 hr later. The results indicated rapid absorption and urinary excretion, but gave no quantitative insights into the extent of absorption (Schierl et al., 1998). Urinary Pt measurements in rats following an acute inhalation of radiolabelled Pt, PtO2, PtCl4 or Pt(SO4)2 (particle diameter around 1 µm) indicated only small fractions of the administered dose were absorbed, even for the two soluble salts. Most of the radiolabel appeared in the faeces, presumably reflecting mucociliary clearance and a lack of significant absorption from the gastrointestinal tract (Moore et al., 1975a).

While it is very unlikely that diammonium hexachloroplatinate will be available to a high extent via the lungs, ECHA guidance notes that "that if data on the starting route (oral) are available these should be used, but for the end route (inhalation), the worst case inhalation absorption should still be assumed (i.e. 100%)". Therefore, the health-precautionary figure of 100% as recommended by ECHA has been taken forward.

No substance-specific data on dermal uptake of diammonium hexachloroplatinate were identified. The high water solubility suggests that significant dermal absorption through intact skin is unlikely. Furthermore, REACH guidance states that a reasonable default assumption is that dermal absorption will not be greater than by the oral route (ECHA, 2012) [i.e. <1% in this case]. However, two in vitro permeation studies on a related soluble platinum salt, dipotassium tetrachloroplatinate, showed a greater degree of absorption [about 5-8%] than this default process would assume. Using a K2PtCl4 solution (0.3 mg Pt/ml in synthetic sweat) and full thickness skin from six donors (three African and three Caucasian), 4.8 and 2.3%, respectively (as mean values), diffused into the skin in 24 hr; the receptor solutions contained a further 3.4 and 0.5%, respectively (Franken et al., 2015). A slightly earlier publication reported mean skin diffusion and receptor solution percentages of 2.2% and 2.3%, respectively, in similar studies on full thickness skin from four Caucasian females (Franken et al., 2014). Apart from these studies, very little information appears to be available regarding dermal absorption of platinum compounds.

Specific expert guidance on the health risk assessment of metals states that "inorganic compounds require dissolution involving dissociation to metal cations prior to being able to penetrate skin by diffusive mechanisms" and, as such, dermal absorption might be assumed to be very low (values of 0.1 and 1.0% are suggested for dry and wet media, respectively) (ICMM, 2007). However, the potential for diammonium hexachloroplatinate to disrupt the skin barrier (potentially facilitating a greater degree of dermal uptake) cannot be ruled out (despite a lack of classification for skin irritation).

Diammonium hexachloroplatinate displayed evidence of skin irritation in both a non-guideline patch test (Middleton, 1978b), and a skin sensitisation study (Middleton, 1977). Irritation, manifesting as swelling of the ear, was also seen in another skin sensitisation test (using the mouse ear swelling test (MEST) method) conducted on disodium hexachloroplatinate, a member of the “hexachloroplatinate(IV) compounds” category (Schuppe et al., 1997b). Furthermore, diammonium hexachloroplatinate was found to be immediately corrosive when instilled into the eyes of rabbits (Berthold, 1994), and is corrosive to metals (Tremain and Atwal, 2011).

Overall, the default values are somewhat conflicting. Absorption in the range of that indicated by oral studies (i.e. <1%), as suggested by ECHA guidance and ICMM (2007), seems to be too low when considering the in vitro studies on human skin (Franken et al., 2014, 2015). However, assuming 100% absorption – on the basis of potential skin barrier disruption – could be considered as overestimating the dermal absorption potential, particularly considering its high water solubility. With particular reference to the Franken et al. studies, and consideration of possible disruption of the skin barrier, a value of 20% dermal absorption is proposed.

Distribution/Metabolism

Once absorbed, distribution of ammonium and hexachloroplatinate ions throughout the body is expected based on a relatively low molecular weight (~444 g/mol) and high water solubility.

In Moore’s study (1975b), platinum was found in the liver and kidney of rats gavaged with radiolabelled-$PtCl_4$, although levels in other organs were not significantly above background. Other investigators have detected Pt in the liver, kidney, spleen, lung and testis following gavage administration (Lown et al., 1980). A range of other studies, summarised by the US EPA, concur with these findings, with the kidney clearly the most significant site of deposition. A similar pattern was observed following inhalation (US EPA, 2009).

Elimination

In rats given gavage doses of radiolabelled-platinum compounds, absorbed Pt was found to be excreted in the urine and faeces (Moore et al., 1975b). However, given that oral absorption was so low, faecal excretion of unabsorbed Pt during the first 1-2 days after administration contributed substantially to the detected levels (US EPA, 2009).

Diammonium hexachloroplatinate is considered to have only a low potential for bioaccumulation based on its physico-chemical properties (especially water solubility of 5000 mg/L; CRC, 2008).

Conclusion

Experimental data suggest that diammonium hexachloroplatinate is likely to be poorly absorbed after administration by the oral route; what small proportion of the substance is taken up is likely to be rapidly excreted. Although inhalation is not anticipated to be a significant route of exposure, inhalation absorption is likely extensive based on its water soluble nature and relatively low molecular weight, as well as limited experimental data. A high dermal bioavailability is unlikely. Nevertheless, the potential of diammonium hexachloroplatinate to disrupt skin barrier function, potentially facilitating increased dermal penetration, cannot be ruled out, especially considering its known corrosivity to metals and to the eyes of rabbits.

Absorption values of 0.5%, 100% and 20% are proposed for the oral, inhalation and dermal routes, respectively, and are considered health-precautionary for use in the calculation of DNEL values.

References not included elsewhere:

ECHA (2012). European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health. Reference: ECHA-2010-G-19-EN. Version 2.1. November 2012.http://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf

ECHA (2014). European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Chapter R.7c: endpoint specific guidance. Version 2.0. November 2014.

Franken A, Eloff FC, du Plessis J, Badenhorst CJ, Jordaan A and Du Plessis JL (2014). In vitro permeation of platinum and rhodium through Caucasian skin. Toxicology in Vitro 28, 1396-1401.

Franken A, Eloff FC du Plessis J, Badenhorst CJ and Du Plessis JL (2015). In vitro permeation of platinum through African and Caucasian skin. Toxicology Letters 232, 566-572.

ICMM (2007). International Council on Mining & Metals. Health risk assessment guidance for metals. September 2007.

Lown BA, Morganti JB, Stineman CH, D'Agostino RB and Massaro EJ (1980). Tissue organ distribution and behavioral effects of platinum following acute and repeated exposure of the mouse to platinum sulfate. Environmental Health Perspectives 34, 203-212.

Moore W, Jr, Malanchuk M, Crocker W, Hysell D, Cohen A and Stara JF (1975a). Whole body retention in rats of different 191Pt compounds following inhalation exposure. Environmental Health Perspectives 12, 35-39.

Moore W, Hysell D, Hall L, Campbell K and Stara J (1975b). Preliminary studies on the toxicity and metabolism of palladium and platinum. Environmental Health Perspectives 10, 63-71.

Moore W, Jr, Hysell D, Crocker W and Stara J (1975c). Biological fate of a single administration of 191Pt in rats following different routes of exposure. Environmental Research 9, 152-158.

Schierl R, Fries HG, van de Weyer C and Fruhmann G (1998). Urinary excretion of platinum from platinum industry workers. Occupational and Environmental Medicine 55, 138-140.

US EPA (2009). United States Environmental Protection Agency. Toxicological review of halogenated platinum salts and platinum compounds in support of summary information on the Integrated Risk Information System (IRIS). January 2009 Draft.
EPA/635/R-08/018.https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=513625

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

The results of studies on acute toxicity after oral administration are summarised in the following table:

Table 5.1. Studies on acute toxicity after oral administration

Method	**Results**	**Remarks**
rat [common species] (Sprague-Dawley [rat]) male/female oral: gavage no guideline followed A single acute oral administration of ammonium hexachloroplatinate was given to rats (first main study) at 500 mg/kg bw (the highest dose causing no deaths in a range-finding study). As a high mortality rate was recorded at this level, a second main study was carried out at 200 mg/kg bw.	approximate LD50: 200 mg/kg bw (male/female) approximate LD50: >200 - <500 mg/kg bw (male) approximate LD50: <200 mg/kg bw (female)	2 (reliable with restrictions) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, (full information in **Annex II**). **Reference** **Middleton JD 1978**

5.2.1.2. Acute toxicity: inhalation

No relevant information available.

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: study scientifically not necessary / other information available

Justification: see ‘Remark’ - Particle size distribution (PSD) data, as measured by simple sieving, indicate that only a small proportion (0.4%) of diammonium hexachloroplatinate is <100 µm (Tremain and Atwal, 2011b). Nevertheless, such data, when considered in isolation, are of only limited value to an assessment of the potential for inhalation exposure. Exposure considerations provide good support for the conclusion that an acute inhalation toxicity study can be waived. Diammonium hexachloroplatinate is classified for respiratory sensitisation (category 1A), and is allocated to the “high” hazard band (for systemic effects following acute inhalation exposure) on the basis that exposure should be strictly contained. Consequently, appropriate safety labelling, personal protection and RMMs/OCs are required, ensuring that the potential for inhalation exposure is strictly controlled. Hence, exposure at levels sufficient to invoke considerations of acute inhalation toxicity is not anticipated. Finally, for animal welfare reasons, conducting new in vivo toxicity tests is considered a last resort. Consequently, no testing by the inhalation route is considered justified.

5.2.1.3. Acute toxicity: dermal

No relevant information available.

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: study scientifically not necessary / other information available

Justification: see ‘Remark’ - No acute dermal toxicity data are available for diammonium hexachloroplatinate. However, the existing in vivo skin sensitisation studies on the compound (Dearman et al., 1998; Middleton, 1977) as well as on the structurally closely-related compound disodium hexachloroplatinate hexahydrate (Schuppe et al., 1997), albeit limited in their assessment of general systemic effects, indicate a lack of acute systemic toxicity following dermal exposure. Exposure considerations provide good support for the conclusion that an acute dermal toxicity study can be waived. First, skin contact during production and/or use is expected to be very low. Second, diammonium hexachloroplatinate is classified for skin sensitisation (category 1B) and is allocated to the “moderate” hazard band (for local effects following acute and long-term dermal exposure), so appropriate safety labelling, personal protection and RMMs/OCs are required. These will ensure that the potential for skin exposure is minimised. Further, diammonium hexachloroplatinate is classified for respiratory sensitisation (category 1A) and the associated RMMs/OCs at the “high” hazard banding, will ensure that airborne levels are strictly controlled, thereby reducing the possibility of dermal exposure further. As such, there are sufficient available data for chemical hazard and risk assessment, classification and labelling, and risk mitigation purposes. Finally, for animal welfare reasons, conducting new in vivo toxicity tests is considered as a last resort. Consequently, in vivo testing is considered a low priority for further work.

5.2.1.4. Acute toxicity: other routes

No relevant information available.

5.2.2. Human information

No relevant information available.

5.2.3. Summary and discussion of acute toxicity

<u>The following information is taken into account for any hazard / risk assessment:</u>

Key Information:

The acute oral LD50 of ammonium hexachloroplatinate is approximately 200 mg/kg bw in rats. Four of five females, but none of five males, died after a single oral dose at this level, suggesting that the LD50 in females maybe somewhat lower than this (Middleton, 1978a).

No relevant acute dermal or inhalation toxicity data were identified.

Value used for CSA:
Acute oral toxicity:
adverse effect observed
(LD50) 200 mg/kg bw
Acute dermal toxicity:
no study available
Acute inhalation toxicity:
no study available

Relevant studies: Acute toxicity: oral (KEY) - Middleton (1978a)

Additional information:

No relevant acute toxicity human data were identified.

The acute toxicity of ammonium hexachloroplatinate was investigated in a well-conducted study Sprague-Dawley rats. Initially, rats (1/sex/group) received the test material via oral gavage at doses of 25, 50, 200, 500 or 2000 mg/kg bw. Both rats died at the top dose within 24 hours; no deaths were seen at the lower doses. Subsequently, 5 rats/sex received the test material at a dose of 500 mg/kg bw (the highest dosecausing no deaths in the range-finding study) by stomach tube. As 4 rats of each sex died within 3 days of administration of the test material at this dose, a second main study (again involving 5 rats/sex) was performed at 200 mg/kg bw. At this level, 4 females died within 24 hours, whilst the remaining animals survived the 14-day observation period. Of the surviving animals at 200 mg/kg bw, pale kidneys were observed in one male and one female; no gross abnormalities were detected in the other 4 animals. The study authors conclude that the acute oral LD50 of ammonium hexachloroplatinate in the rat is “likely to be in the region of 200 mg/kg bw”, and classed the test substance according to Hodge and Sterner (1943) as “moderately toxic”. Four of five females, but none of five males, died after a single oral dose of 200 mg/kg bw, suggesting that the LD50 in females may be somewhat below 200 mg/kg bw and in males is greater than 200 mg/kg bw (but less than 500 mg/kg bw). The possible sensitivity of females to ammonium hexachloroplatinate in this test system was not discussed by the study authors (Middleton, 1978a). Based on the results of this study, the test material should be classified for acute oral toxicity (category 3) according to EU CLP criteria (EC 1272/2008).

No acute inhalation toxicity data were identified. However, as the compound is classified for respiratory sensitisation (category 1A), the corresponding safety/protective measures will ensure that the potential for inhalation exposure is strictly controlled. Hence, exposure at levels sufficient to invoke considerations of acute inhalation toxicity is not anticipated.

Similarly, no acute dermal toxicity data were identified. However, as the compound is classified for skin sensitisation (category 1B), the corresponding safety/protective measures will ensure that the potential for skin exposure is minimised. Moreover, skin contact during production and/or use is expected to be negligible.

Justification for classification or non classification:

Based on the results of the available and reliable acute oral rat study, diammonium hexachloroplatinate should be classified for acute oral toxicity (category 3) according to EU CLP criteria (EC 1272/2008).

No evidence of specific target organ toxicity was noted. As such, classification for STOT-SE is not considered appropriate.

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

The results of studies on skin irritation are summarised in the following table:

Table 5.2. Studies on skin irritation

Method	**Results**	**Remarks**
rabbit [common species] (New Zealand White [rabbit]) Coverage: occlusive (Backs of the rabbits were shaved (not “closely clipped” as recommended by the OECD guidelines). One site of each rabbit was abraded immediately before application of the test material, the other site remained intact.) according to guideline Skin irritation patch test, as described in Federal Register 1973, Vol. 38, No. 187, Section 1500: 41. 0.5 g of material was applied on a gauze pad to abraded and non-abraded skin of six albino rabbits. The site was covered with adhesive tape. The sites were examined after 24 and 72 hours for erythema and oedema.	slightly irritating - Migrated information not irritant by EU criteria Criteria used for interpretation of results: other: Classified “according to the US Federal Register 1973 skin test” primary dermal irritation index (PDII) 1.3 of max. 8 (Time point: 24 and 72 hrs after initial application) Reversibility: Reversibility not assessed, as observation period only 48 hrs (not up to 14 days as recommended in the OECD guidelines)	2 (reliable with restrictions) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Middleton JD 1978**

Studies with results indicating corrosivity to the skin are summarised in section 5.4 Corrosivity.

<u>**Data waiving**</u>

Information requirement: Skin Irritation

Reason: study scientifically not necessary / other information available

Justification: an in vitro skin irritation study does not need to be conducted because adequate data from an in vivo skin irritation study are available [study scientifically not necessary / other information available]

5.3.1.2. Human information

No relevant information available.

5.3.2. Eye

5.3.2.1. Non-human information

The results of studies on eye irritation are summarised in the following table:

Table 5.3. Studies on eye irritation

Method	Results	Remarks
rabbit (White Russian (albino)) Vehicle: unchanged (no vehicle) according to guideline OECD Guideline 405 (Acute Eye Irritation / Corrosion) ; according to guideline EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion)	Category I - Migrated information Criteria used for interpretation of results: EU An irritation index could not be determined because of the corrosive effects. not fully reversible within: 7 days in two of the animals positive indication of irritation - An irritation index could not be determined because of the corrosive effects	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Berthold K 1994**

<u>Data waiving</u>

Information requirement: Eye Irritation

Reason: study scientifically not necessary / other information available

Justification: an in vitro eye irritation study does not need to be conducted because adequate data from an in vivo eye irritation study are available [study scientifically not necessary / other information available]

5.3.2.2. Human information

No relevant information available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No relevant information available

5.3.3.2. Human information

No relevant information available.

5.3.4. Summary and discussion of irritation

The following information is taken into account for any hazard / risk assessment:

Key Information:

In an early US guideline study, ammonium hexachloroplatinate (0.5 g) was applied (24-hr, occluded) to the shaved abraded and intact skin of six rabbits. Slight but reversible indications of irritation to intact skin were observed in three animals during the observation period (Middleton, 1978b).

In a guideline study, to GLP, instillation of ammonium hexachloroplatinate (0.1 ml) into one eye of each of three rabbits caused severe irritation and corrosion (Berthold, 1994).

No relevant respiratory tract irritation data were identified.

Value used for CSA:
Skin irritation / corrosion: adverse effect observed (irritating) Eye irritation: adverse effect observed (irreversible damage) Respiratory irritation: no study available

Relevant studies: Skin irritation / corrosion, in vivo (KEY) - Middleton (1978b)

Relevant studies: Eye irritation, in vivo (KEY) - Berthold (1994)

Additional information:

No relevant human irritation/corrosion data were identified. No in vitro skin or eye irritation studies were identified, or are required, as reliable in vivo studies are already available.

In a US Federal Register Patch Test (1973), the skin irritant potential of ammonium hexachloroplatinate was assessed in six female New Zealand White rabbits. The test material (0.5 g) was applied (occluded) to the shaved abraded and intact skin for 24 hr. The sites were assessed for evidence of erythema (and eschar) formation and oedema formation immediately upon removal of the patch, and again 48 hr later. Three intact skin sites showed evidence of erythema/oedema which was observed to be reversible (or showed indications of reversibility) during the observation period. No signs of irritation were apparent on the other three intact sites. Two abraded skin sites showed evidence of possible necrosis associated with the abrasions in the skin. A Primary Irritation Score of 1.3 (out of 8) was obtained. The study authors classified ammonium hexachloroplatinate as a mild skin irritant in this test system (Middleton, 1978b). This study suffered from a number of significant deviations from those given in the current OECD guidelines, including use of abraded skin, no moistening of test substance (a powder) to ensure good skin contact, a longer exposure period and failure to wash off any residual test material after removal of patch, observation period was insufficient to assess reversibility of effects, and skin was only examined on 2 occasions, at 0 and 48 hr, rather than at 1, 24, 48 and 72 hr, after patch removal. However, certain of these deviations are likely to increase the possibility of an irritant reaction, so the study can be considered as likely more sensitive than the current methodology to identify potential irritants.

In an in vivo eye irritation study carried out in accordance with OECD Test Guideline 405, and to GLP, a 0.1 ml aliquot of undiluted ammonium hexachloroplatinate was instilled into the conjunctival sac of the right eye of three White Russian rabbits (one male, two females). The left eye was untreated to serve as a control. Following instillation the eyelids were held closed by gentle finger pressure. The ocular response was assessed at 1, 24, 48 and 72 hours and thereafter once daily for up to 21 days. Corneal opacity, effects on the iris and conjunctival redness, chemosis and discharge were scored according to the Draize numerical scale. Any clinical signs of toxicity were noted and body weights were also recorded. The treated eye as well as eye lids and nictitating membrane were assessed microscopically. A number of severe (and often irreversible) effects were observed, including opacity and necrosis of the cornea, moderate circumcorneal hyperaemia of the iris, diffuse redness of the conjunctiva, swelling of the eyelids, as well as ocular discharge and the formation of a white mucus over the eyes. Two animals were killed 7 days after application because of the severe effects observed. The histopathological examination revealed a pronounced irritation potential of the test material, leading to very severe coagulation necrosis after conjunctival application. An irritation index could not be determined because of the corrosive effects. No systemic toxicity was observed other than a very slight reduction in body weight in the two rabbits showing corrosive effects (Berthold, 1994).

No respiratory tract irritation data were identified. A new study was not conducted as it is not a REACH Standard Information Requirement.

Justification for classification or non classification:

Based on the results of the available and reliable skin and eye irritation studies in rabbits, diammonium hexachloroplatinate does not warrant classification for skin irritation, but should be classified for serious eye damage (category 1) under EU CLP criteria (EC 1272/2008).

5.4. Corrosivity

5.4.1. Non-human information

No relevant information available.

5.4.2. Human information

No relevant information available.

5.4.3. Summary and discussion of corrosion

Skin irritation / corrosion, in vivo (KEY) - Middleton (1978b)
The studies with results indicating corrosivity are discussed in section 5.3.4 Summary and discussion of irritation.

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

The results of studies on skin sensitisation are summarised in the following table:

Table 5.4. Studies on skin sensitisation

Method	Results	Remarks
skin sensitisation: in vivo (non-LLNA) guinea pig	GHS criteria not met No. with positive reactions: 1st reading :	1 (reliable without restriction)

(not specified) female Induction: intradermal and epicutaneous Vehicle: saline for the induction injection, and petroleum jelly for the topical applications (induction and challenge phase) Induction: Vehicle: equivalent or similar to guideline OECD Guideline 406 (Skin Sensitisation)	8 out of 10 (test chemical ; 24 h after challenge; dose: 10%) (Reading: 1st reading. . Hours after challenge: 24.0. Group: test group. Dose level: 10%. No with. + reactions: 8.0. Total no. in groups: 10.0.) No. with positive reactions: 2nd reading : 2 out of 10 (test chemical ; 48 h after challenge; dose: 10%) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: test group. Dose level: 10%. No with. + reactions: 2.0. Total no. in groups: 10.0.) No. with positive reactions: 1st reading : 1 out of 4 (negative control ; 24 h after challenge; dose: 10%) (Reading: 1st reading. . Hours after challenge: 24.0. Group: negative control. Dose level: 10%. No with. + reactions: 1.0. Total no. in groups: 4.0.) No. with positive reactions: 2nd reading : 1 out of 4 (negative control ; 48 h after challenge; dose: 10%) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: negative control. Dose level: 10%. No with. + reactions: 1.0. Total no. in groups: 4.0.) No. with positive reactions: rechallenge : 0 out of 10 (test chemical ; 24 h after challenge; dose: 5%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: test group. Dose level: 5%. No with. + reactions: 0.0. Total no. in groups: 10.0.) No. with positive reactions: rechallenge : 0 out of 4 (negative control ; 24 h after challenge; dose: 5%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: negative control. Dose level: 5%. No with. + reactions: 0.0. Total no. in groups: 4.0.) No. with positive reactions: rechallenge : 0 out of 10 (test chemical ; 24 h after challenge; dose: 1%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: test group. Dose level: 1%. No with. + reactions: 0.0. Total no. in groups: 10.0.) No. with positive reactions: rechallenge : 0 out of 4 (negative control ; 24 h after challenge; dose: 1%) (Reading: rechallenge. . Hours after challenge: 24.0. Group: negative control. Dose level: 1%. No with. + reactions: 0.0. Total no. in groups: 4.0.)	weight of evidence experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, (full information in **Annex II**). **Reference** **Middleton JD 1977**

skin sensitisation: in vivo (LLNA) mouse (Balb/c [mouse]) female Local lymph node assay no guideline followed Similar in methodology to local lymph node assay (LLNA), but measuring cytokine production (not lymph node cell proliferation). Aim was to explore the selective activation of different cytokine profiles in comparison to those provoked by a known respiratory allergen (TMA) and a known contact allergen (DNCB).	Sensitising - Cytokine profile indicative of Th2-type immediate-type hypersensitivity : (Cytokine analyses were comparable to those seen with the respiratory allergen trimellitic anhydride (TMA) and the contact allergen 2,4 -dinitrochlorobenzene (DNCB))	2 (reliable with restrictions) weight of evidence experimental study **Test material** Ammonium hexachloroplatinate IV, Form: dissolved in DMSO (full information in **Annex II**). **Reference** **Dearman RJ et al. 1998**
skin sensitisation: in vivo (LLNA) mouse (Balb/c [mouse]) female Local lymph node assay equivalent or similar to guideline OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay) Local lymph node (auricular lymph node; ALN) assay to detect primary immune response.	Sensitising - Based on expert judgment ALN index: 22.8 (caused a 23-fold increase in number of ALN (auricular lymph node) proliferating cells, and a 4 -fold increase in global ALN cell yield per animal compared to vehicle controls. This response was comparable to that seen in the positive control)	2 (reliable with restrictions) weight of evidence experimental study **Test material** Disodium hexachloroplatinate hexahydrate; Na2[PtCl6].6H2O, Form: not specified (full information in **Annex II**). **Reference** **Schuppe H-C et al. 1997**
skin sensitisation: in vivo (LLNA) mouse (Balb/c [mouse]) female Local lymph node assay equivalent or similar to guideline OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay) Local lymph node (auricular lymph node; ALN) assay to detect primary immune response.	Sensitising - Based on expert judgment ALN index: 22.8 (caused a 23-fold increase in number of ALN (auricular lymph node) proliferating cells, and a 4 -fold increase in global ALN cell yield per animal compared to vehicle controls. This response was comparable to that seen in the positive control)	2 (reliable with restrictions) weight of evidence Read-across from study conducted on a member of the “hexachloroplatinate (IV) compounds” category, disodium hexachloroplatinate **Test material** Diammonium hexachloroplatinate, (full information in **Annex II**). **Reference**

		Schuppe H-C et al. 1997
Justification for type of information: Disodium hexachloroplatinate is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		
skin sensitisation [deactivated phrase] - in vivo mouse (Balb/c [mouse]) female no guideline available Repeated application of test compound to one ear of mice followed by challenge on other ear. Extent of swelling on the challenged ear was used to assess skin sensitising potential.	Sensitising - Based on expert judgment	2 (reliable with restrictions) weight of evidence experimental study **Test material** Disodium hexachloroplatinate hexahydrate; Na2[PtCl6].6H2O, Form: not specified (full information in **Annex II**). **Reference** **Schuppe H-C et al. 1997**
skin sensitisation [deactivated phrase] - in vivo mouse (Balb/c [mouse]) female no guideline available Repeated application of test compound to one ear of mice followed by challenge on other ear. Extent of swelling on the challenged ear was used to assess skin sensitising potential.	Sensitising - Based on expert judgment	2 (reliable with restrictions) weight of evidence Read-across from study conducted on a member of the “hexachloroplatinate (IV) compounds” category, disodium hexachloroplatinate **Test material** Diammonium hexachloroplatinate, (full information in **Annex II**). **Reference** **Schuppe H-C et al. 1997**
Justification for type of information: Disodium hexachloroplatinate is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		

Data waiving

Information requirement: Skin Sensitisation

Reason: study scientifically not necessary / other information available

Justification: An in vitro skin sensitisation study does not need to be conducted because adequate data from an in vivo skin sensitisation study are available.

5.5.1.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 5.5. Exposure-related observations on skin sensitisation in humans

Method	Results	Remarks
Study type: survey Type of population: occupational Subjects: Workers in a catalyst production plant where different types of production activities were carried out involving solubilizing "platinum metals" in closed reactors. The resulting solutions were used to produce intermediates (dust, granules, pellets, beads) and finished products (catalysts for transport and domestic electrical appliances) through impregnation of different substrates and calcination in kilns. Additionally precious metals were refined from exhaust catalysts after a combustion cycle. Various jobs in the plant resulted in exposure to platinum classified into 3 levels: - production of platinum salts, solution and refining (high exposure) - all other production workers (low exposure) - office workers outside the production area (no exposure) 153 employees examined 137 men, 16 women Mean age 34 years (range 21-60 years) no guideline required Occupational exposure to platinum salts; skin prick and patch testing with hexachloroplatinic acid and sodium hexachloroplatinate, each at >99.2% purity, to determine the prevalence and clinical characteristics of hypersensitivity among 153 workers in a catalyst production plant	Skin prick tests with platinum salts gave positive responses in 22/153 workers (14%): 8 reacted to all 3 platinum salts tested, 4 to both hexachloroplatinic acid and potassium tetrachloroplatinate, 3 to both hexachloroplatinic acid and sodium hexachloroplatinate, 7 to hexachloroplatinic acid only Of the 22 workers with positive skin prick tests to hexachloroplatinic acid, 1 also had a positive patch test; 1 further individual with a negative skin prick test to hexachloroplatinic acid had a positive patch test Of the total of 23 workers with a skin reaction to hexachloroplatinic acid, incidences were 0/11 (0%), 14/105 (13%) and 9/37 (24%) in the no, low and high exposure groups respectively; the adjusted prevalence odds ratio for the high exposure group (compared with the low exposure group) was 2.4 (95% confidence limits 0.8-6.9). Incidences were 7/72 (10%) and 16/70 (23%) in those employed for 0-5 and 6-30 years respectively; adjusted prevalence odds ratio 3.2 (95% CI 1.2-8.9) Clinical characteristics of the 23 workers with positive skin responses to hexachloroplatinic acid included rhinitis (n=1), asthma (n=10), urticaria (n=5) and eczema (n=2) [some subjects had more than one symptom; results not presented in relation to exposure level] "Descriptive analysis demonstrates that asthma and urticaria are more frequent in subjects allergic to Pt-salts, while rhinitis and dermatitis commonly belong to allergies of common inhalants as well as allergies to Pt-salts."	2 (reliable with restrictions) weight of evidence migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** Sodium hexachloroplatinate; disodium hexachloroplatinate(2-) / 16923-58-3 / 240-983-5; hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full information in **Annex II**). **Reference** **Cristaudo A et al. 2005**
Study type: survey Type of population: occupational Subjects: Workers in a catalyst production plant. Production process involved preparation of platinum salt solution in a closed system, immersion of various substrates in the solution by robots in the encapsulated impregnation area, reduction in a furnace. Total population: total number of persons in cohort from which the subjects were drawn - 222 exposed subjects; 86 control subjects 10 subjects from the catalyst department (6%), 11 craftsmen with frequent jobs in the catalyst department (20%) and 30 controls (35%) refused to complete the study; 23 catalyst department subjects (14%), 9	Conversion from negative to positive skin prick test response to hexachloroplatinic acid occurred in 13 subjects in the high exposure category and 1 subject in the persistent low exposure category (although some high exposure had also been experienced by this individual); incidence was 4.1 conversions/100 person-years; for newly-employed subjects (n=10), incidence was 5.9 conversions/100 person-years; for existing employees (n=3), incidence was 2.1 conversions/100 person-years; multivariate analysis showed strong association between skin prick test conversion and exposure category (p=0.011); also statistically significant positive association for smoking (relative risk 3.9, 95% confidence interval	2 (reliable with restrictions) weight of evidence migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full information in **Annex II**).

craftsmen (17%) and 15 controls (17%) left the plant during the study; 4 catalyst department subjects (2%) had a positive response to the skin prick test with hexachloroplatinic acid at the initial assessment and were excluded from the study. Total number of subjects in study: 209 exposed subjects: 159 from the catalyst department, 50 craftsmen with frequent jobs in the catalyst department. 66 control subjects from the canteen, administration, security staff at the plant and newly-employed blue-collar workers from other departments at the plant. Participation rate: 95% of catalyst department subjects, 93% of craftsmen with frequent jobs in the catalyst department, 77% of controls. High exposure: total n=115; 104 catalyst department workers, 11 craftsmen; mean age 32 years (95% confidence interval 30-34); 115/115 (100%) male; 53 smokers, 38 ex-smokers, 24 non-smokers, mean of 9 pack-years (95% CI 7-11) Persistent low exposure: total n=51; 51 catalyst department workers; mean age 32 (95% CI 29-35); 48/51 (94%) male; 16 smokers, 12 ex-smokers, 23 non-smokers, mean of 6 pack-years (95% CI 4-8) Intermittent low exposure: total n=61; 4 catalyst department workers, 38 craftsmen, 19 controls; mean age 39 years (95% CI 36-42); 60/61 males (98%); 18 smokers, 19 ex-smokers, 24 non-smokers, mean of 9 pack-years (95% CI 6-12) No exposure: total n=48; 1 craftsman, 47 controls; mean age 38 years (95% CI35-41); 41/47 males (85%); 16 smokers, 16 ex-smokers, 16 non-smokers, mean of 11 pack-years (95% CI 7-15) Atopy occurred with similar frequency in all groups no guideline required Prospective cohort study. “To assess both the exposure to [platinum] and the incidence of sensitization to [platinum] salt in a catalyst production plant in a 5-year prospective cohort study and to possibly define a threshold value for sensitization.”	1.6-9.7). Symptoms (asthma, rhinitis, conjunctivitis, dermatitis) beginning during the study occurred more frequently in the high exposure category; frequency of at least 1 of the symptoms 35/115 (33%) high exposure, 6/61 (12%) persistent low exposure, 3/61 (5%) intermittent low exposure, 4/48 (8%) no exposure No other differences in results (total IgE, FEV1, bronchial hyperresponsiveness) between exposure groups	**Reference** **Merget R et al 2000**

5.5.2. Respiratory system

5.5.2.1. Non-human information

The results of studies on respiratory sensitisation are summarised in the following table:

Table 5.6. Studies on respiratory sensitisation

Method	Results	Remarks
mouse (Balb/c [mouse]) female Local lymph node assay Induction: dermal - 3 doses of 100 uL on the shaved back; 3 doses of 25 uL/ear. Challenge: oropharyngeal aspiration Vehicle: DMSO - for induction (topical)/saline for challenge (inhalation). no guideline available Female BALB/c mice were administered the test substance (ammonium hexachloroplatinate (AHCP), 1% in DMSO) on the shaved back on test days 0, 5 and 15, and on the ears on test days 10, 11 and 12. Control animals received the vehicle only. The mice were challenged with AHCP (10, 31 or 100 ug in saline) by oropharyngeal aspiration on test days 24 and 29. Immediate responses to the test substance challenge were measured using whole-body plethysmography (WBP). Additionally, WBP was used to measure responses to the non-specific bronchoconstrictor acetyl-beta-methylcholine chloride (Mch) on test days 26 and 31. Lymph node cell counts, eosinophil content in bronchoalveolar lavage fluid (BALF), and total serum immunoglobulin E (IgE) were also assessed.	sensitising Respiratory challenge with the mid- and high-doses of AHCP (31 and 100 ug) resulted in a dose-dependent increase in the number of lymph node cells present in the auricular lymph nodes. This number increased significantly with a second challenge with 10, 31 or 100 ug AHCP. “An antigen-specific immediate response was evident in AHCP-sensitised mice following the first OPA challenge on day 24 with 31 and 100 ug AHCP [...] Immediate responses were similar in mice receiving a second OPA challenge with AHCP on day 29.” The lungs were also responsive to non-specific stimuli (Mch) on challenge. The proportion of eosinophils in the BALF, a marker of allergic inflammation, increased from <0.5% in non-sensitised mice to about 5% in dermally pre-sensitised mice, challenged with AHCP. Total serum IgE levels were significantly elevated in in platinum pre-sensitised mice, compared to non-sensitised mice, when measured on day 19 and 26.	2 (reliable with restrictions) supporting study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: not specified (full information in **Annex II**). **Reference** **Williams WC, Lehmann JR, Boykin E, Selgrade MK and Lehmann DM 2015**

5.5.2.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 5.7. Exposure-related observations on respiratory sensitisation in humans

Method	Results	Remarks
Study type: survey Type of population: occupational Subjects: Workers in a catalyst production plant where different types of production activities were carried out involving solubilizing “platinum metals” in closed reactors. The resulting solutions were used to produce intermediates (dust, granules, pellets, beads) and finished products (catalysts for transport and domestic electrical appliances) through impregnation of different substrates and calcination in kilns. Additionally precious metals were refined from exhaust catalysts after a combustion cycle. Various jobs in the plant resulted in exposure to platinum classified into 3 levels: - production of platinum salts,	Skin prick tests with platinum salts gave positive responses in 22/153 workers (14%): 8 reacted to all 3 platinum salts tested, 4 to both hexachloroplatinic acid and potassium tetrachloroplatinate, 3 to both hexachloroplatinic acid and sodium hexachloroplatinate, 7 to hexachloroplatinic acid only Of the 22 workers with positive skin prick tests to hexachloroplatinic acid, 1 also had a positive patch test; 1 further individual with a negative skin prick test to hexachloroplatinic acid had a positive patch test Of the total of 23 workers with a skin reaction to hexachloroplatinic acid, incidences were 0/11 (0%), 14/105 (13%) and 9/37 (24%) in the no, low and high exposure groups respectively; the adjusted prevalence odds ratio for the high exposure	2 (reliable with restrictions) weight of evidence migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** Sodium hexachloroplatinate; disodium hexachloroplatinate(2-) / 16923-58-3 / 240-983-5;

solution and refining (high exposure) - all other production workers (low exposure) - office workers outside the production area (no exposure) 153 employees examined 137 men, 16 women Mean age 34 years (range 21-60 years) no guideline required Occupational exposure to platinum salts; skin prick and patch testing with hexachloroplatinic acid and sodium hexachloroplatinate, each at >99.2% purity, to determine the prevalence and clinical characteristics of hypersensitivity among 153 workers in a catalyst production plant	group (compared with the low exposure group) was 2.4 (95% confidence limits 0.8-6.9). Incidences were 7/72 (10%) and 16/70 (23%) in those employed for 0-5 and 6-30 years respectively; adjusted prevalence odds ratio 3.2 (95% CI 1.2-8.9) Clinical characteristics of the 23 workers with positive skin responses to hexachloroplatinic acid included rhinitis (n=1), asthma (n=10), urticaria (n=5) and eczema (n=2) [some subjects had more than one symptom; results not presented in relation to exposure level] “Descriptive analysis demonstrates that asthma and urticaria are more frequent in subjects allergic to Pt-salts, while rhinitis and dermatitis commonly belong to allergies of common inhalants as well as allergies to Pt-salts.”	hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full information in **Annex II**). **Reference** **Cristaudo A et al. 2005**
Study type: survey Type of population: occupational Subjects: - Number of subjects exposed: 65 - Sex: 63 men, 2 women - Age: Mean 37.2 years (SD 10.8 years) no guideline available Cross-sectional study to investigate the prevalence of allergic respiratory tract diseases in 65 workers in a German chemical plant processing platinum, with exposure to platinum salts.	Work-related symptoms (conjuntivitis, rhinitis, coughing, respiratory distress) were recorded in 15/65 (23%) of workers, 11/21 (52%), 1/23 (4%) and 3/21 (14%) in the high, moderate and low exposure groups respectively (statistically significant difference between high exposure group and the other two groups p<0.01); the symptoms occurred outside work in 10 further individuals (15%); 40 workers (62%) were without symptoms. For skin prick testing, a positive response to potassium hexachloroplatinate was recorded for 12/64 workers tested (19%), 9/14 (64%) in those with work-related symptoms, 2/10 (20%) in those who experienced symptoms outside work and 1/40 (2.5%) in those without symptoms. Total IgE and platinum-specific IgE were significantly higher in those with work-related symptoms; histamine release in response to potassium hexachloroplatinate was not. In subjects with work-related symptoms, normal lung function was seen on Monday mornings, but this fell to below normal during the shift and during the working week; resistance was unchanged. For work-related symptoms (conjunctivitis, rhinitis, coughing, respiratory distress), latency time from beginning of exposure to onset: mean (+/- SD) 4.8 (+/-3.9) years (range 1-13 years). No information in paper regarding whether assessment of symptoms was made with or without knowledge of exposure group.	2 (reliable with restrictions) weight of evidence experimental study **Test material** Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Bolm-Audorff U. et al. 1992**
Study type: survey Type of population: occupational Subjects: Workers in a catalyst production plant. Production process involved preparation of platinum salt solution in a	Conversion from negative to positive skin prick test response to hexachloroplatinic acid occurred in 13 subjects in the high exposure category and 1 subject in the persistent low exposure category (although	2 (reliable with restrictions) weight of evidence migrated information:

closed system, immersion of various substrates in the solution by robots in the encapsulated impregnation area, reduction in a furnace. Total population: total number of persons in cohort from which the subjects were drawn - 222 exposed subjects; 86 control subjects 10 subjects from the catalyst department (6%), 11 craftsmen with frequent jobs in the catalyst department (20%) and 30 controls (35%) refused to complete the study; 23 catalyst department subjects (14%), 9 craftsmen (17%) and 15 controls (17%) left the plant during the study; 4 catalyst department subjects (2%) had a positive response to the skin prick test with hexachloroplatinic acid at the initial assessment and were excluded from the study. Total number of subjects in study: 209 exposed subjects: 159 from the catalyst department, 50 craftsmen with frequent jobs in the catalyst department. 66 control subjects from the canteen, administration, security staff at the plant and newly-employed blue-collar workers from other departments at the plant. Participation rate: 95% of catalyst department subjects, 93% of craftsmen with frequent jobs in the catalyst department, 77% of controls. High exposure: total n=115; 104 catalyst department workers, 11 craftsmen; mean age 32 years (95% confidence interval 30-34); 115/115 (100%) male; 53 smokers, 38 ex-smokers, 24 non-smokers, mean of 9 pack-years (95% CI 7-11) Persistent low exposure: total n=51; 51 catalyst department workers; mean age 32 (95% CI 29-35); 48/51 (94%) male; 16 smokers, 12 ex-smokers, 23 non-smokers, mean of 6 pack-years (95% CI 4-8) Intermittent low exposure: total n=61; 4 catalyst department workers, 38 craftsmen, 19 controls; mean age 39 years (95% CI 36-42); 60/61 males (98%); 18 smokers, 19 ex-smokers, 24 non-smokers, mean of 9 pack-years (95% CI 6-12) No exposure: total n=48; 1 craftsman, 47 controls; mean age 38 years (95% CI35-41); 41/47 males (85%); 16 smokers, 16 ex-smokers, 16 non-smokers, mean of 11 pack-years (95% CI 7-15) Atopy occurred with similar frequency in all groups no guideline required Prospective cohort study. “To assess both the exposure to [platinum] and the incidence of sensitization to [platinum] salt in a catalyst production plant in a 5-year prospective cohort study and to	some high exposure had also been experienced by this individual); incidence was 4.1 conversions/100 person-years; for newly-employed subjects (n=10), incidence was 5.9 conversions/100 person-years; for existing employees (n=3), incidence was 2.1 conversions/100 person-years; multivariate analysis showed strong association between skin prick test conversion and exposure category (p=0.011); also statistically significant positive association for smoking (relative risk 3.9, 95% confidence interval 1.6-9.7). Symptoms (asthma, rhinitis, conjunctivitis, dermatitis) beginning during the study occurred more frequently in the high exposure category; frequency of at least 1 of the symptoms 35/115 (33%) high exposure, 6/61 (12%) persistent low exposure, 3/61 (5%) intermittent low exposure, 4/48 (8%) no exposure No other differences in results (total IgE, FEV1, bronchial hyperresponsiveness) between exposure groups	read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full information in **Annex II**). **Reference** **Merget R et al 2000**

possibly define a threshold value for sensitization.”		
Study type: survey Type of population: occupational Subjects: Total number of persons in cohort from which data were generated: 547 (in 3 process areas); sub-group of chemical processs operators (CPOs; exposed to soluble platinum for at least 50% of their work) identified within each exposure group, total n=341 EXPOSURE DATA - DURATION New employees who started work between 01-Jan-1976 and 31-Dec-1995, followed up until 31-Dec-1995, were considered for inclusion the study. Criteria for inclusion: - no previous exposure to soluble platinum compounds - work gave regular exposure to soluble platinum compounds which required subjects to undergo medical surveillance - employed for long enough to have at least one medical examination (these were performed every 3 months) - CATEGORIES 3 exposure categories to airborne soluble platinum: - PGM refinery (n=406, CPOs=270); workers exposed to chloroplatinates, but not TPC; lowest Pt exposure of the 3 groups - TPC lab (n=41; CPOs=31); workers regularly exposed to TPC and chloroplatinates; highest Pt exposure of the 3 groups - Autocat (n=100; CPOs=40); exposure to TPC only; group with intermediate Pt exposure SUBJECT DESCRIPTION PGM refinery: total n=406; 373 men, 33 women; mean age 29 years (range 18-61); 199 smokers; 1 atopic TPC lab: total n=41; 40 men, 1 woman; mean age 25 years (range 17-47); 11 smokers; 0 atopic Autocat: total n=100; 85 men, 15 women; mean age 26 years (range 16-61); 33 smokers; 4 atopic A sub-group of chemical processs operators (CPOs; exposed to soluble platinum for at least 50% of their work) was identified within each exposure group, with the following characteristics: - PGM refinery: total n=270; 257 men, 13 women; mean age 30 years (range 18-59); 164 smokers; 0 atopic; - TPC lab: total n=31; 31 men, 0 women; mean age 25 years (range 17-47); 9 smokers; 0 atopic; - Autocat: total n=40; 40 men, 0 women; mean age 29 years (range 16-61); 17 smokers; 0 atopic MEDICAL SURVEILLANCE ROUTINE Enquiry about symptoms and skin prick tests every 3 months with 3 platinum salts	FULL COHORT PGM refinery (lowest exposure to airborne soluble platinum, exposure to chloroplatinates only, i.e. not TPC): 110/406 cases of sensitisation (27%); 106/270 cases (39%) in the CPO sub-group TPC lab (highest exposure to airborne soluble platinum, exposure to chloroplatinates and TPC): 5/41 cases of sensitisation (12%); 5/31 cases (16%) in the CPO sub-group; probability of sensitisation was significantly less than in the PMG refinery (p<0.05), relative risk (with 95% confidence interval) reported as 0.33 (0.14-0.78). Autocat (intermediate exposure to airborne soluble platinum, exposure to TPC only): 0/100 cases of sensitisation (0%); 0/40 cases (0%) in the CPO sub-group; probability of sensitisation was significantly less than in the PMG refinery (p<0.001) and the TPC lab (p<0.05), relative risk 0.00 CPO SUB-GROUP PGM refinery, no relationship between probability of sensitisation and age at the start of employment; strong evidence of a relationship with smoking; smoking-adjusted RRs (with 95% CI) for the TPC lab and the Autocat groups, compared with the PGM refinery group, were 0.47 (0.20-1.12; not statistically signficant) and 0.00 (p<0.001) PGM refinery (lowest exposure to airborne soluble platinum, exposure to chloroplatinates only, i.e. not TPC): median time to diagnosis of sensitisation 13 months (range 1-108 months); 80/106 cases diagnosed in first 2 years of employment; 1.4 cases/100 person-months in the first 5 years of employment TPC lab (highest exposure to airborne soluble platinum, exposure to TPC and chloroplatinates): median time to diagnosis of sensitisation 37 months (range 7-52 months); 0.5 cases/100 person-months in the first 5 years of employment Autocat (intermediate exposure to airborne soluble platinum, exposure to TPC only): no cases of sensitisation in CPO sub-group or this group in the original cohort Sensitisation incidence calculations were restricted to first 60 months of employment to prevent long-term “survivor” bias.	2 (reliable with restrictions) weight of evidence experimental study **Test material** Chloroplatinates & Tetaammine platinum dichloride (TPC), Form: Airborne [possibly particulate matter] (full information in **Annex II**). **Reference** **Linnett PJ & Hughes EG 1999**

(ammonium hexachloroplatinate up to 1994, sodium hexachloroplatinate throughout, sodium tetrachloroplatinate up to 1992, TPC from 1992 onwards) at 10 mg/ml in glycerol carbol saline or 0.9% saline; spirometry every 6 months. Positive responses (> or = to 2 mm dimaeter weal) were followed up with further testing. SUBJECT TRANSFERS 11 employees (8 CPOs) from the PMG refinery transferred to the Autocat; 1 CPO from the TPC group and 1 from the Autocat transferred to the PGM refinery. Subjects who transferred between operations were considered to have withdrawn at the date of transfer and were not included in the analysis for the operation to which they transferred. no guideline available Longitudinal/cohort study Analysis of 20 year data on exposure to soluble platinum compounds [including chloroplatinates - known potent allergens] and medical surveillance results primarily to confirm that the soluble compound tetraammine platinum dichloride is not allergenic.		
Study type: survey Type of population: occupational Subjects: - Number of subjects exposed: 1036 (the number of newly hired workers over the study duration was 1040, but for 4 of these workers, no information about their job history was available, or they had a job title for which no exposure estimate could be generated; hence the number of newly exposed workers was 1036) - Sex: 876 males and 164 females - Age: Average of 32.4 years - Race: No data - Demographic information: No data no guideline available Retrospective cohort study to evaluate the quantitative exposure-response relation between occupational exposure to soluble platinum (used as a surrogate for chloroplatinate exposure) and sensitization	In total, 1763 exposure measurements were available for analysis. Overall geometric mean levels of chloroplatinate are given per refinery in Table 1 (see below). Overall, information was available for more than 2000 workers, and the population size varied from around 100 to more than 1000 between refineries. Little more than 50% (1040) of all subjects started working since January 1, 2000. Incidence rates for platinum sensitization overall and by exposure category are shown in Table 2 (see below). On average, subjects were followed for 3.9 years. On average, cases became sensitized after 2.5 person years of follow-up, with a minimum of 0.36 (almost 4.5 months) and a maximum of 9.9 years. Overall, 2.4 cases were seen per 100 years of follow-up, with clear differences between refineries in sensitization rates but also between exposure categories between atopic and nonatopic subjects, smokers and nonsmokers, and men and women. Site 3 had the lowest sensitization rate, and this was also the site with the lowest prevalence of atopy and rigid pre-employment selection of nonsmokers at baseline for employment. At site 5, the atopy prevalence was similar to that of the general population, but the smoking prevalence at baseline was relatively low. Survival modeling of incidence data showed that	1 (reliable without restriction) weight of evidence experimental study **Test material** Chloroplatinum salts (as soluble platinum), Form: Airborne [possible total dust as opposed to inhalable fraction] (full information in **Annex II**). **Reference** **Heederik D, Jacobs J, Samadi S, van Rooy F, Portengen L and Houba R 2016**

	exposure-response relations were observed for ‘‘current’’ exposure, as well as average and cumulative exposure, Table 3 (see below). The correlation between current and average exposure was very high (0.98), and thus associations between these exposure proxies and the incidence of sensitization can only be marginally different. The correlation between cumulative exposure and current and average exposure was considerably lower (0.72 and 0.74, respectively). Thus workers were reclassified considerably when using cumulative exposure instead of current or average exposure. For all 3 exposure measures, a gradually increasing risk was observed with increasing exposure, but for average exposure, the risk was reduced in the highest exposure category. The risk ratios (RRs) for both atopy and smoking were statistically significantly different from 1, with RRs of between 1.5 and 2. The relationship was strongest for current and average exposure, and weaker for cumulative exposure. For current exposure categories of ≤49, >49-≤100, >100-≤252 and >252 ng/m3, RRs were 1 (reference), 1.4, 2.2 and 3.2, respectively, the latter two values being statistically significant (p<0.005 or better). For average exposure, RRs were 1, 1.8, 4.2 and 3.0, respectively, for the ≤51.1, >51.1-≤105, >105-≤250 and >250 ng/m3 categories (all statistically significant, p<0.05 or better). Sex, refinery and age were not introduced as parameters in the final models. Interactions between atopy and exposure and smoking and exposure did not yield statistically significant interaction variables in addition to the main effects for exposure, atopy, and smoking, respectively. Thus the final model contained atopy, smoking, and exposure as main effects only. Analyses using penalized splines generally produced a more refined picture than analysis with categorical exposure data. A clear monotonic increasing exposure-response relation was seen for current platinum salt exposure up to a level of 200 ng/m3 and a leveling off at considerably higher exposure levels. Average exposure resulted in a similar exposure-response relation, but there was a tendency toward a slightly reduced risk at very high exposure levels. The use of cumulative exposure as an exposure proxy led to considerable recategorization of the population, and this resulted in a clear bell-shaped exposure-response relation. After a peak in sensitization risk between 1000 and 2000 ng/m3 per year, the risk was	

	clearly reduced at higher cumulative exposures, indicating that susceptible subjects had become sensitized and were probably exhausted in the population, resulting in a survivor population.	

5.5.3. Summary and discussion of sensitisation

The following information is taken into account for any hazard / risk assessment:

Skin sensitisation

Key Information:

Occupational studies of exposed workers, together with many case reports, provide good evidence that certain soluble halogenated platinum salts are skin sensitisers. Urticaria (Type I immediate hypersensitivity) is most commonly reported, while allergic contact dermatitis appears to be rare. Results from laboratory animal studies support the human evidence. Skin sensitisation potential is essentially limited to complexes where halogen ligands are coordinated to the platinum atoms; hexachloroplatinic acid and the tetra- and hexa-chloroplatinate salts are mainly responsible for platinum-salt skin sensitisation.

Allergic respiratory tract sensitisation following occupational exposure to complex halogenated platinum compounds, in particular the chloroplatinates, is a well-established health hazard. Available epidemiology data have not yet permitted delineation of an induction threshold for complex halogenated platinum salt sensitivity (PSS) in workplace exposure scenarios.

Value used for CSA: adverse effect observed (sensitising)

Relevant studies: Skin sensitisation, GPMT (WoE) - Middleton (1977)
Relevant studies: Skin sensitisation, LLNA (WoE; read-across) - Schuppe et al. (1997)
Relevant studies: Skin sensitisation, MEST (WoE; read-across) - Schuppe et al. (1997)
Relevant studies: Skin sensitisation, LLNA (WoE) - Dearman et al. (1998)

Relevant studies: Respiratory sensitisation, (Support) - Williams et al. (2015)
Additional information:

No in vitro skin sensitisation studies were identified, or are required, as reliable in vivo studies are already available.

The development of skin sensitisation following occupational exposure to halogenated platinum compounds, in particular chloroplatinates, is a well-established health hazard, and has been addressed in comprehensive expert reviews (HCN, 2008; IPCS, 1991; SCOEL, 2011; US EPA, 2009; WHO, 2000, 2012). The following brief summary is based largely on information cited in these reviews and focuses on the key information to indicate an appropriate classification category according to the skin sensitisation criteria of Regulation (EC) No. 1272/2008, as amended.

WHO (2012) noted that urticaria (Type I immediate hypersensitivity) and allergic contact dermatitis are symptoms of platinum-specific allergic skin sensitisation in numerous case reports and occupational health studies on workers exposed to halogenated platinum salts (Baker et al., 1990; Bolm-Audorff et al., 1992; Calverley et al., 1995, 1999; Cristaudo et al., 2005; Hunter et al., 1945; IPCS, 1991; Marshall, 1952; Merget, 2000, Merget et al., 1988, 1999, 2000; Pepys, 1984; Pepys et al., 1972; WHO, 2000). Reactions are generally urticarial and eczematous in nature, while true allergic contact dermatitis from exposure to platinum compounds is rare (HCN, 2008). SCOEL and HCN noted that skin sensitisation potential is limited to complexes where halogen ligands are coordinated to the platinum atoms; hexachloroplatinic acid and the tetra- and hexa-chloroplatinate salts are mainly responsible for platinum-salt skin sensitisation. Uncharged complexes and complexes with ligands other than halogens appear to lack such potential (HCN, 2008; SCOEL, 2011).

Merget et al. (2000) reported the results of a 5-year prospective cohort study that found a dose-response relationship between airborne soluble platinum concentrations and newly occurring sensitisation cases. The study was performed during 1989-1995 (more than 20 years ago), and included 275 employees of a catalyst-production plant in Germany, of whom 115 worked in the production lines (‘high exposure’), 112 worked (regularly or irregularly) within the catalyst department but not in the production lines (‘low exposure’), and 48 never entered the catalyst building (‘no exposure’). 53% of the study population were already present when the study started. The subjects had undergone at least two examinations and had a negative response in a skin prick test against platinum at the initial survey. The results demonstrated that in a population of 160 workers, no new cases of sensitisation occurred during 5-year employment in the ‘no exposure’ and ‘low exposure’ areas but, in the ‘high exposure’ area, 14 new cases of sensitisation occurred in 115 exposed workers (11%). Smoking cigarettes was positively associated with the occurrence of new symptoms. It was concluded that exposures below the OEL value (generally 2000 ng Pt/m3) may still result in sensitisation (Merget et al., 2000) and WHO stated that “Qualitative evaluation of these data would suggest that halogenated platinum salts are potent or strong skin sensitizers” (WHO, 2012). However, the investigators themselves acknowledged that the study was not designed to establish a threshold for sensitisation induction and could not be used to establish an OEL (Merget et al., 2000). The major issues over characterisation of exposure were addressed in an industry report (EPMF, 2009) and SCOEL (2011) noted that the study was not conducted with the aim to find a no-observed-adverse-effect level (NOAEL), peak exposures were not quantified, high past exposures may have contributed to the sensitisation cases, exposure estimates were not based on the sampling, and exposures were highly variable, all of which may lead to unreliable exposure estimates. SCOEL concluded that “the database does not allow the recommendation of an OEL for soluble platinum compounds” (SCOEL, 2011).

More recently, a new epidemiological study (Heederik et al., 2016) has provided better insights into respiratory sensitisation risk at low exposures (see the section on Respiratory Sensitisation, below), but did not focus on skin sensitisation aspects.

Although a guinea pig maximization test found no evidence of skin sensitisation potential for ammonium hexachloroplatinate (Middleton, 1977), three published laboratory animal studies (Dearman et al., 1998; Schuppe et al., 1997) provide support for the view that halogenated platinum salts are dermal sensitisers. Schuppe et al. (1997) reported a significant positive reaction in BALB/c mice exposed to 5% sodium hexachloroplatinate in a LLNA (adapted to avoid the use of radioactive label) and in a modified ear swelling test (MEST). At that 5% concentration, the ALN Index (which presumably reflects the Stimulation Index (SI)) in the LLNA test exceeded 3 [the level used to differentiate sensitisers from non-sensitisers]. If that concentration is used as the EC3 [the effective concentration required to induce a 3-fold increase in the proliferation of lymph node cells compared with vehicle-treated controls], then the potency category for this halogenated platinum salt would be in the moderate range [CLP Sub-category 1B]. Lower (unspecified) concentrations evidently did not increase the ALN Index (Schuppe et al., 1997). Disodium hexachloroplatinate is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report. Dearman et al. (1998) reported increases in production of interferon-g expression [typical of a skin sensitiser; Th1 response] and interleukin (IL-10) [characteristic of respiratory sensitizers; Th2 response] for diammonium hexachloroplatinate when applied to the ears of BALB/c mice at exposure concentrations down to 0.25%. In isolation, these results might indicate a potency category of strong [Sub-category 1A]. However, Dearman et al. (1998) only evaluated cytokine release, and the experiment did not include a LLNA or development of EC3 values. In addition, it should be noted that both the LLNA and MEST in isolation are unable to differentiate between immediate (Th2 type) and delayed (Th1 type) hypersensitivity responses.

Most reports do not include (dermal or inhalation) exposure data, making thresholds for induction impossible to determine. In respect of elicitation, in one study a positive skin reaction was elicited by skin patch application of 15 µl of a 0.01M solution of hexachloroplatinic acid, in 2 of 153 workers at a catalyst manufacturing and recycling factory; 22 had a positive skin prick test (SPT) indicative of IgE antibody involvement to the same substance (Cristaudo et al., 2005). Although data on suitable patch test concentrations are limited, WHO (2012) noted that published occupational data are available on challenge doses associated with a positive SPT response to halogenated platinum salts. Two cited papers reported that the lowest exposure concentration of halogenated platinum salts required to elicit a positive SPT ranged from 10−9 to 10−3 g/ml (six orders of magnitude) among individuals previously sensitised to halogenated platinum salts (Biagini et al., 1985; Brooks et al., 1990).

WHO felt that the low elicitation dose for halogenated platinum salts, based on SPT and occupational exposure data suggests that these salts sit at the higher end of sensitiser potency. WHO also concluded that the published laboratory animal data suggest that the potency category for some halogenated platinum salts would be moderate or strong (WHO, 2012). Overall, the significant data gaps and inadequate dermal exposure data preclude determination of an elicitation dose threshold for halogenated platinum salts, and there is little information to inform a qualitative evaluation. Published data on low exposures are inadequate to evaluate whether some halogenated platinum salts might be classified as strong sensitizers.

As indicated above, assays such as LLNA and MEST cannot differentiate between Th2 and Th1 immune responses and therefore in the case of the chloroplatinates positive responses do not necessarily indicate that delayed contact hypersensitivity has been induced. There is significant published evidence (e.g. Dearman et al., 1998), and unpublished data within the industry sector, which strongly suggests that the Th2 arm is preferentially induced on skin exposure to chloroplatinate salts and related Pt compounds. Extensive accumulated industrial experience from health surveillance systems in the platinum group metal sector indicates that exposure to complex halogenated salts of platinum, typified by soluble hexa- and tetra-chloroplatinates, results in the preferential induction of Th2 (IgE-mediated) responses in sensitisation reactions. These data encompass a sector historical record of more than 50 years, involving over 10 companies.

These chloroplatinate induced Th2-type responses involve activation of specific subsets of T lymphocytes and the cytokine products of these cells can be tracked with cytokine fingerprinting in both experimental toxicology studies and human clinical investigations. The end result of such activation is allergen-specific IgE antibody production, and the predominant reaction in symptomatic workers is respiratory sensitisation and/or allergic rhinoconjunctivitis, with contact urticaria being less commonly observed. In contrast, allergic contact dermatitis (ACD) as a result of non-IgE mediated mechanisms (i.e. Th1-based responses) has been rarely observed, particularly in terms of its occurrence in isolation from immediate hypersensitivity responses. It is estimated that ACD incidence accounts for <1% of symptomatic cases in sensitised worker populations.

Taking into account extensive human industrial experience of exposure to this substance where skin contact does not routinely result in allergic contract dermatitis (but can cause Th2 immediate hypersensitivity), the weight of evidence indicates that classification as Sub category 1B is appropriate for this substance (personal communication Johnson Matthey).

Several chloroplatinate compounds are being registered under REACH by the PMC: dipotassium tetrachloroplatinate (CAS RN 10025-99-7); dipotassium hexachloroplatinate (CAS RN 16921 30-5); diammonium hexachloroplatinate (CAS RN 16919-58-7); and hexachloroplatinic acid (CAS RN 16941-12-1).

Occupational health studies, supported by case reports, provide sufficient evidence that halogenated platinum salts can induce skin sensitisation responses in exposed workers. Laboratory animal studies provide additional support for this potential. From the limited available data, dermal exposure thresholds for induction and elicitation cannot be robustly determined. The limited nature of the existing exposure data also precludes quantifying any relationship between dermal and inhalation exposure in inducing skin sensitisation. There is extensive evidence that these skin reactions can be mediated by Th2-type responses in humans, and this is supported by cytokine release profiles, SPT responses, and industry data indicative of IgE involvement. Therefore, it can be concluded that the available evidence is not supportive of the chloroplatinates having potent delayed contact hypersensitivity potential, and that the weight of evidence indicates the chloroplatinates should be classified as Sub-category 1B (low to moderate frequency of occurrence). In a recent non-guideline study, it was demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational skin sensitisation and respiratory sensitisation/asthma, further supporting the decision to formulate a qualitative assessment approach (and consequent ‘high hazard’ banding) as most appropriate for the respiratory and dermal sensitisation endpoints.

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<u>Discussion of human information:</u>
See “Summary and discussion of human information” in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT

<u>The following information is taken into account for any hazard / risk assessment:</u>

<u>Respiratory sensitisation</u>

Value used for CSA: adverse effect observed (sensitising)
Additional information:

The development of allergic respiratory tract sensitisation following occupational exposure to halogenated platinum compounds, in particular chloroplatinates, is a well-established health hazard, and has been addressed in comprehensive expert reviews (HCN, 2008; IPCS, 1991; SCOEL, 2011; US EPA, 2009; WHO, 2000, 2012). The following brief summary is based largely on information cited in these reviews and focuses on the key information to indicate an appropriate classification category under the revised respiratory sensitisation criteria of Regulation (EC) No. 1272/2008, as amended.

Adverse occupational health effects following exposure to complex platinum salts have been reported as far back as a century ago (Karasek and Karasek, 1911). It was reported that 52 out of 91 (57%) precious metal workers in four British platinum refineries had symptoms of sneezing, wheezing and shortness of breath when exposed at airborne levels of between 0.9 and 1700 µg/m3 (Hunter et al., 1945).

A WHO (2012) evaluation cited a large number of case reports and occupational studies that identify the health effects in workers exposed to halogenated platinum salts – in particular certain chloroplatinates – as asthma, rhinitis and conjunctivitis (Baker et al., 1990; Bolm Audorff et al., 1992; Calverley et al., 1995; Cristaudo et al., 2005; Hunter et al., 1945; IPCS, 1991; Marshall, 1952; Merget, 2000; Merget et al., 1988, 1999, 2000; Pepys, 1984; Pepys et al., 1972; WHO, 2000). The WHO (2012) review noted that additional reports provide support for one or more of the above effects, consistent with respiratory sensitisers: viz asthma (Brooks et al., 1990; Merget et al., 1991, 1994, 1995, 1996), respiratory difficulties (Karasek and Karasek, 1911), inflammatory changes in the respiratory tract (Merget et al., 1996; Roberts, 1951), bronchospasm (Calverley et al., 1999) and bronchial hyperactivity (Biagini et al., 1985; Brooks et al., 1990; Merget et al., 1991). A similar extensive list of relevant reports is provided in US EPA (2009). Asymptotic respiratory sensitisation (detected by skin prick testing; SPT) can proceed to occupational asthma and rhinitis if exposure is continued, and such symptoms may be severe (Friedman-Jimenez et al., 2000; Merget et al., 1999). Severe cases of allergic sensitisation to halogenated platinum salts have included workers with bluish skin due to insufficient oxygen in the blood, feeble pulse, and extreme breathing difficulty, requiring the subject to maintain an upright position to breath (Roberts, 1951). Review of published epidemiology indicates that for chloroplatinate salts, latency from first exposure to the evidence of respiratory sensitisation varies from a few months to about ten years, with the majority occurring within approximately 3 years (Cochrane et al., 2015; HCN, 2008; IPCS, 1991; SCOEL, 2011; US EPA, 2009; WHO, 2000, 2012).

The respiratory sensitisation effects detected in the workplace have been attributed to complex halogenated salts, where the platinum atom is directly coordinated to halide atoms, and not where the halide, such as chloride, is present in ionic form (Cochrane et al., 2015; HCN, 2008; SCOEL, 2011; US EPA, 2009). The work environment of a platinum refinery or platinum catalyst production plant where individuals become sensitised to platinum compounds evidently primarily involves exposure to halogenated platinum salts, mainly chloroplatinates, ammonium tetrachloroplatinate, ammonium hexachloroplatinate, sodium hexachloroplatinate, potassium tetrachloroplatinate, potassium hexachloroplatinate or hexachloroplatinic acid (Cochrane et al., 2015; Heederik et al., 2016; Hunter et al., 1945; Merget et al., 1999, 2000; Parrot et al., 1969).

The allergenic potential may be related to the degree of chlorination (Cleare et al., 1976; Cristaudo et al., 2005; Linnett and Hughes, 1999). Results from laboratory animal studies provide data supporting a relationship between allergenic potential and the degree of chlorination (Murdoch and Pepys, 1984a,b, 1985, 1986; Schuppe et al., 1992, 1997; WHO, 2012), and some data suggest that there is a correlation between activity and the degree of chlorination between the series of hexachloroplatinate and tetrachloroplatinate salts.

From the various studies carried out to date (early 2016), it has not been possible to define a robust induction threshold for respiratory sensitisation in occupationally-exposed humans. WHO (2000) noted that the incidence of PSS fell following the adoption of an occupational exposure limit (OEL) with a threshold limit value (TLV) for soluble platinum salts of 2 µg/m3 (as Pt) as an 8-hour time-weighted average (TWA). However, several epidemiological studies have reported respiratory tract sensitisation in chloroplatinate workers even where the estimated workplace air concentrations were below this 2 µg/m3 OEL (Baker et al., 1990; Bolm-Audorff et al., 1992; Heederik et al., 2016; Linnett and Hughes, 1999; Merget et al., 2000).

In recent Expert Group attempts to evaluate respiratory sensitisation risk at low exposures to complex halogenated platinum salts (SCOEL, 2011; US EPA, 2009), an epidemiological study by Merget et al. (2000) played a central role. However, the investigators themselves acknowledged that the study was not designed to establish a threshold for PSS induction and could not be used to establish an OEL (Merget et al., 2000). The major issues over characterisation of exposure were addressed in an industry report (EPMF, 2009) and SCOEL (2011) was unable to recommend an OEL based on this study. More recently, a new epidemiological study (Heederik et al., 2016) has provided better insights into respiratory sensitisation risk at low exposures.

The older Merget et al. (2000) publication reported the results of a 5-year prospective cohort study that found a dose-response relationship between airborne soluble platinum concentrations and newly occurring sensitisation cases. The study was performed during 1989-1995 (more than 20 years ago), and included 275 employees of a catalyst-production plant in Germany, of whom 115 worked in the production lines (‘high exposure’), 112 worked (regularly or irregularly) within the catalyst department but not in the production lines (‘low exposure’), and 48 never entered the catalyst building (‘no exposure’). 53% of the study population were already present when the study started. The subjects had undergone at least two examinations and had a negative response in a skin prick test against platinum at the initial survey. The results demonstrated that in a population of 160 workers, no new cases of sensitisation occurred during 5-year employment in the ‘no exposure’ and ‘low exposure’ areas [The SCOEL (2011) summary of Merget et al. (2000) stated that the maximum concentrations of soluble platinum measured in the ‘low-exposure’ area were 8.6 and 1.5 ng/m3 in 1992 and 1993, respectively. In the ‘high exposure’ area, the maximum measured concentrations of soluble platinum were roughly 700 and 155 ng/m3 in 1992 and 1993, respectively. Personal sampling (of inhalable dust) in this area revealed a median value of 177 ng/m3 with a highest value of 3700 ng/m3; 3 samples out of 22 exceeded 2000 ng/m3 (8-hour sampling time). It was concluded that exposures below the occupational threshold limit value (generally 2000 ng Pt/m3) may still result in sensitisation; even exposure to soluble platinum salts at levels between 10 and 100 ng Pt/m3 may lead to sensitisation (Merget et al., 2000). However, important issues in regard to the exposure characterisation presented in this paper were subsequently noted (EPMF, 2009)] but, in the ‘high exposure’ area, 14 new cases of sensitisation occurred in 115 exposed workers (11%). Smoking cigarettes was positively associated with the occurrence of new symptoms. It was concluded that exposures below the OEL value (generally 2000 ng Pt/m3) may still result in sensitisation (Merget et al., 2000). Based on these results, SCOEL suggested that at exposure to levels below 10 ng/m3 sensitisation is not to be expected. Critically, SCOEL noted that the study was not conducted with the aim to find a no-observed-adverse-effect level (NOAEL), peak exposures had not been quantified, high exposures may have occurred in the past which could have contributed to the sensitisation cases, exposure estimates were not based on the sampling, and exposures were highly variable, all of which may lead to unreliable exposure estimates. SCOEL concluded that “the database does not allow the recommendation of an OEL for soluble platinum compounds” (SCOEL, 2011).

A recently-published retrospective cohort study designed to investigate PSS found a clear exposure-response relationship between chloroplatinate salts and respiratory sensitisation in workers. The study involved about 1040 refinery workers who newly joined one of five refineries during an 11-year period (1 January 2000 to 31 December 2010), and for whom a total of around 1760 personal time-weighted average exposure measurements (to soluble platinum; used as a surrogate for the various chloroplatinate intermediates in particulate and liquid aerosol forms) were available. Only personal time-weighted average measurements based on the inhalable or total dust fraction, and approximating to 8-hour workshift values were included in the exposure database. Sensitisation cases were detected by SPT, using a hexachloroplatinate salt, which is a method with high sensitivity and predictivity. The relationship was strongest for current (recent) and average exposure, and weaker for cumulative exposure. For current exposure categories of ≤49, >49 ≤100, >100-≤252 and >252 ng/m3, Risk Ratios (RRs) were 1 (reference), 1.4, 2.2 and 3.2, respectively, the latter two values being statistically significant (p<0.005 or better). For average exposure, RRs were 1, 1.8, 4.2 and 3.0, respectively, for the ≤51.1, >51.1-≤105, >105 ≤250 and >250 ng/m3 categories (all statistically significant at p<0.05 or better). The investigators concluded that “the exposure-relation for current exposure is characterized by an initial steep increase in risk starting at low exposure levels and levelling off at levels of greater than 200 ng/m3” (Heederik et al., 2016).

This recent, high-quality study (Heederik et al., 2016) is consistent with other epidemiology studies in demonstrating that PSS can be induced at estimated airborne soluble platinum concentrations (as a chloroplatinate surrogate measure) of less than 2 µg/m3 (2000 ng/m3) as an 8-hour TWA value. Although the study possessed higher statistical power than any previous epidemiology investigation of PSS, due to some limitations in the low-end exposure dataset it was not possible to define a robust induction threshold (airborne critical concentration) for respiratory sensitisation to chloroplatinates.

In summary, there is extensive epidemiological evidence (from cohort studies and case reports) that halogenated platinum salts, in particular chloroplatinates, can act as respiratory sensitisers, with a large proportion of the exposed workers developing symptoms if the occupational levels are sufficiently high. On continued exposure, asymptomatic respiratory sensitisation (detected by SPT) can proceed to occupational asthma and rhinitis, and such symptoms may be severe. There is a lack of information with regards the particular compounds involved, but the human data, together with supporting laboratory animal studies, indicate the more highly chlorinated forms such as hexachloroplatinate and tetrachloroplatinate are more active as respiratory sensitisers than the less chlorinated forms.

Several chloroplatinate compounds are being registered under REACH by the PMC: dipotassium tetrachloroplatinate (CAS RN 10025-99-7); dipotassium hexachloroplatinate (CAS RN 16921 30-5); diammonium hexachloroplatinate (CAS RN 16919-58-7); and hexachloroplatinic acid (CAS RN 16941-12-1). Given the frequency of occurrence of respiratory sensitisation in workers exposed to sufficiently high occupational levels, and the severity of the symptoms that may develop, particularly if exposure is continued, the available data indicate that it is appropriate to classify these substances as respiratory sensitisers, in sub-category 1A, according to EU CLP criteria. The available epidemiology data have not yet permitted delineation of an induction threshold for PSS in workplace exposure scenarios. In a recent non-guideline study, it was demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational respiratory sensitisation/asthma, further supporting the decision to formulate a qualitative assessment approach (and consequent ‘high hazard’ banding) as most appropriate for the respiratory and dermal sensitisation endpoints.

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Justification for classification or non classification:

The well-known and extensive data set for halogenated platinum compounds indicates that classification for both skin and respiratory sensitisation are required for diammonium hexachloroplatinate.

As discussed above, available evidence is not supportive of diammonium hexachloroplatinate having potent delayed contact hypersensitivity potential. The weight of evidence indicates that this compound should be classified for skin sensitisation in sub-category 1B (low to moderate frequency of occurrence), according to EU CLP criteria (EC 1272/2008).

Given the high frequency of occurrence of respiratory sensitisation in workers exposed to sufficiently high occupational levels of chloroplatinates, and the severity of the symptoms that may develop, particularly if exposure is continued, the available data would indicate that it is appropriate to classify diammonium hexachloroplatinate as a respiratory sensitiser, in sub-category 1A, according to EU CLP criteria (EC 1272/2008).

Discussion of human information:
See “Summary and discussion of human information” in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of studies are summarised in the following table:

Table 5.8. Studies on repeated dose toxicity after oral administration

Method	**Results**	**Remarks**
rat [common rodent species] (Crj: CD(SD) [rat]) male/female short-term repeated dose toxicity: oral oral: gavage Doses / Concentrations: 10 mg/kg bw/day Basis: actual ingested Doses / Concentrations: 30 mg/kg bw/day Basis: actual ingested Doses / Concentrations: 100 mg/kg bw/day Basis: actual ingested Vehicle: corn oil Exposure: 28 days. (Once daily.) according to guideline OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents) ; according to guideline EU Method B.7 (Repeated Dose (28 Days) Toxicity (Oral))	NOAEL: 10 mg/kg bw/day (actual dose received) (male/female) based on: (test mat.) No general systemic effects seen at 10 mg/kg bw/day LOAEL: 30 mg/kg bw/day (actual dose received) (male) based on: (test mat.) Reduction in body weight gain compared to control group.	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Hansen B 2015**

5.6.1.2. Repeated dose toxicity: inhalation

No relevant information available.

5.6.1.3. Repeated dose toxicity: dermal

No relevant information available.

5.6.1.4. Repeated dose toxicity: other routes

No relevant information available.

5.6.2. Human information

No relevant information available.

5.6.3. Summary and discussion of repeated dose toxicity

The following information is taken into account for any hazard / risk assessment:

Key Information:

In an OECD Test Guideline 407 study, to GLP, rats (5/sex/group) were administered diammonium hexachloroplatinate by gavage for 28 days. The systemic toxicity NOAEL was 10 mg/kg bw/day on the basis of clinical signs of toxicity (including reduced body weight and growth) in the mid and high dose groups (30 and 100 mg/kg bw/day), resulting in morphological changes to the kidneys and stomach (Hansen, 2015a).

In support, in an OECD Test Guideline 421 reproductive/developmental toxicity screening study, rats (12/sex/group) were administered diammonium hexachloroplatinate by oral gavage at doses of 0, 10, 30 or 100 mg/kg bw/day for at least 35 days. The study NOAEL was established to be 30 mg/kg bw/day for systemic toxicity (Hansen, 2015b).

No repeated dose toxicity studies by the inhalation or dermal route were identified, or are required.

Value used for CSA (via oral route - systemic effects):
adverse effect observed
(NOAEL: 10mg/kg bw/day; subacute, rat [common rodent species])

Relevant studies: Repeated dose toxicity: oral (KEY) - Hansen (2015a)

Value used for CSA (inhalation - systemic effects):
no study available

Relevant studies: Repeated dose toxicity: oral (KEY) - Hansen (2015a)

Value used for CSA (inhalation - local effects):
no study available

Relevant studies: Repeated dose toxicity: oral (KEY) - Hansen (2015a)

Value used for CSA (dermal - systemic effects):
no study available

Relevant studies: Repeated dose toxicity: oral (KEY) - Hansen (2015a)

Value used for CSA (dermal - local effects):
no study available

Relevant studies: Repeated dose toxicity: oral (KEY) - Hansen (2015a)

Additional information:

No relevant human data were identified.

In a 28-day repeated dose oral toxicity study, conducted according to OECD Test Guideline 407 and to GLP, rats (5/sex/group) were gavaged with diammonium hexachloroplatinate via stomach tube at doses of 0 (vehicle control, given corn oil), 10, 30 or 100 mg/kg bw/day. Rats were observed for signs of toxicity and mortality, and changes in body weight. Neurobehaviour was assessed (using a functional observation battery). On day 29, blood samples were collected for the analysis of haematological parameters and clinical chemistry. This was immediately followed by sacrifice and scheduled necropsy, in which a comprehensive range of organs and tissues were examined macroscopically and microscopically. Males in the mid-dose group had reduced body weight and body weight gain, compared to controls, and mid-dose females were found to have histopathological lesions in the kidneys (tubular basophilia and hyaline casts) and stomach. In the high-dose group, body weights and body weight gain were affected in both sexes, and lesions of the kidneys and stomach had increased in incidence and severity. Additional findings were noted in the kidney (lymphocytic infiltration, fibrosis, tubular dilation and tubular necrosis) and stomach (lympho-histio-granulocytic infiltration, lymphocytic or eosinophilic infiltration, and/or a chronic/subacute and ulcerative inflammation) at the high dose. Furthermore, high-dose animals were observed to be salivating after treatment. Other clinical signs of toxicity in high-dose females were piloerection, reduced motility, reduced amount of faeces, hunched posture, haemorrhagic nose and/or snout and a decreased body temperature. Under the conditions of this study, the no-observed-adverse-effect level (NOAEL) for systemic toxicity was 10 mg/kg bw/day (Hansen, 2015a).

In support, in a GLP OECD Test Guideline 421 reproductive/developmental toxicity screening study, rats (12/sex/group) were administered diammonium hexachloroplatinate by oral gavage at doses of 0, 10, 30 or 100 mg/kg bw/day for at least 35 days. Parental (F0) animals were observed for clinical signs of toxicity throughout the study, with body weights and food consumption monitored. At necropsy, animals were subjected to external and internal macroscopic examinations for any abnormalities or pathological changes. Special attention was paid to the reproductive organs. Two females in the high-dose group died prematurely. Surviving high-dose animals displayed slight to extreme salivation, piloerection, and/or pale faeces were reported. Increased water consumption was observed in high-dose males. Salivation and piloerection were also observed in low- and mid-dose animals. In the high-dose group, body weights were significantly reduced compared to controls, and cellular changes to the stomach and kidneys were also reported. No test item-related microscopic changes were noted in the reproductive organs at any dose level. The study NOAEL was established to be 30 mg/kg bw/day for systemic toxicity (Hansen, 2015b).

According to REACH Annex VIII (EC 1907/2006), repeated dose toxicity studies only need to be conducted on one species taking into consideration the most appropriate route of administration regarding human exposure.

Justification for classification or non classification:

Based on the histopathological effects on the kidney observed at 30 mg/kg bw/day and above in the 28-day rat study, diammonium hexachloroplatinate should be classified as STOT RE1 according to EU CLP criteria (EC 1272/2008). The observed effects on the stomach are likely the result of local irritancy.

Detailed information on the Mode of Action is available in **Annex III.**

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

The results of in vitro genotoxicity studies are summarised in the following table:

Table 5.9. In vitro genotoxicity studies:

Method	Results	Remarks
mammalian cell gene mutation assay [gene mutation] (in vitro gene mutation study in mammalian cells - Type of genotoxicity: gene mutation) Chinese hamster Ovary (CHO) [mammalian cell line] (without met. act.) Test concentrations: Including 10 and 60 uM [possibly 1-100 µM] Positive control substance(s): ethylmethanesulphonate equivalent or similar to guideline OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) [in vitro gene mutation study in mammalian cells]	Test results: positive - weak for Chinese hamster Ovary (CHO) [mammalian cell line]; met. act.: without genotoxicity: positive - weak cytotoxicity: cytotoxicity - not significant at 10 uM; growth/cloning efficiency reduced by 50% at 34/50 uM, respectively vehicle controls valid: negative controls valid: valid positive controls valid: valid	2 (reliable with restrictions) key study experimental study **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, Form: In [presumably aqueous] solution (full information in **Annex II**). **Reference** **Taylor R. T. et al. 1979**
mammalian cell gene mutation assay [gene mutation] (in vitro gene mutation study in mammalian cells - Type of	Test results: positive - weak for Chinese hamster	2 (reliable with restrictions) key study

genotoxicity: gene mutation) Chinese hamster Ovary (CHO) [mammalian cell line] (without met. act.) Test concentrations: Including 10 and 60 uM [possibly 1-100 µM] Positive control substance(s): ethylmethanesulphonate equivalent or similar to guideline OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) [in vitro gene mutation study in mammalian cells]	Ovary (CHO) [mammalian cell line]; met. act.: without genotoxicity: positive - weak cytotoxicity: cytotoxicity - not significant at 10 uM; growth/cloning efficiency reduced by 50% at 34/50 uM, respectively vehicle controls valid: negative controls valid: valid positive controls valid: valid	Read-across from study conducted on a member of the “hexachloroplatinate (IV) compounds” category, dipotassium hexachloroplatinate **Test material** Diammonium hexachloroplatinate, (full information in **Annex II**). **Reference** **Taylor R. T. et al. 1979**
Justification for type of information: Dipotassium hexachloroplatinate is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study - Type of genotoxicity: other: chromosome damage (micronuclei)) mammalian cell line, other: Human peripheral mononuclear blood cells (lymphocytes) [mammalian cell line] (without met. act.) Test concentrations: Concentrations of 0, 5, 10, 20 or 40 µM Positive control substance(s): mitomycin C according to guideline non standard method as described by Fenech M (1993) Mut Res 285, 35-44 ; equivalent or similar to guideline OECD Guideline 487 (In vitro Mammalian Cell Micronucleus Test) [in vitro cytogenicity / micronucleus study]	Test results: negative for mammalian cell line, other: Human peripheral mononuclear blood cells (lymphocytes) [mammalian cell line]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity - Toxicity reported at 40 µM vehicle controls valid: negative controls valid: positive controls valid:	2 (reliable with restrictions) key study experimental study **Test material** K2PtCl6; Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Gebel T et al. 1997**
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study - Type of genotoxicity: other: chromosome damage (micronuclei)) mammalian cell line, other: Human peripheral mononuclear blood cells (lymphocytes) [mammalian cell line] (without met. act.) Test concentrations: Concentrations of 0, 5, 10, 20 or 40 µM Positive control substance(s):	Test results: negative for mammalian cell line, other: Human peripheral mononuclear blood cells (lymphocytes) [mammalian cell line]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity - Toxicity reported at 40 µM vehicle controls valid: negative controls valid: positive controls valid:	2 (reliable with restrictions) key study Read-across from study conducted on a member of the “hexachloroplatinate (IV) compounds” category, dipotassium hexachloroplatinate **Test material** Diammonium

mitomycin C according to guideline non standard method as described by Fenech M (1993) Mut Res 285, 35-44 ; equivalent or similar to guideline OECD Guideline 487 (In vitro Mammalian Cell Micronucleus Test) [in vitro cytogenicity / micronucleus study]		hexachloroplatinate, (full information in **Annex II**). **Reference** **Gebel T et al. 1997**
Justification for type of information: Dipotassium hexachloroplatinate is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study - Type of genotoxicity: other: chromosome damage) lymphocytes: from whole blood donated by two young, non-smoker, males [primary culture] (not specified met. act.) Test concentrations: Up to at least 125 uM Pt Positive control substance(s): mitomycin C ; griseofulvin Assay based on the capability of xenobiotics to induce micronuclei (MN) in human lymphocytes from whole blood, blocking cells in cytokinesis by cytochalasin B. MN frequency evaluated in binucleated lymphocytes and MN analysed for the presence of a fluorescent signal by considering a labelled MN as centromere-positive MN (C+MN). Fluorescence in situ hybridisation (FISH) technique with an alphoid centromere-specific DNA probe was applied in order to clarify the mechanism of action.	Test results: positive for lymphocytes: [primary culture]; met. act.: not specified genotoxicity: positive cytotoxicity: not specified vehicle controls valid: not specified negative controls valid: positive controls valid: not specified	4 (not assignable) supporting study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: not specified (full information in **Annex II**). **Reference** **Migliore L et al 1999**
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium, other: TA97a, TA98, TA100 and TA102 [bacteria] (with and without met. act.) Test concentrations: The test substance was dissolved in distilled water and diluted to 5-500 ug/plate [or possibly 10, 50, 100 or 500 ug/plate] in all four tester strains, in the absence or presence of (4% and 10%) S9. The number of revertant colonies on the plates were recorded after 48 hours of incubation in the dark at 37degC. Positive control substance(s):	Test results: positive for S. typhimurium, other: TA97a, TA98, TA100 and TA102 [bacteria]; met. act.: with genotoxicity: positive cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid: Test results: positive for S. typhimurium, other: TA97a, TA98, TA100 and TA102 [bacteria]; met. act.: without genotoxicity: positive cytotoxicity: cytotoxicity	2 (reliable with restrictions) weight of evidence experimental study **Test material** (NH4)2PtCl6; 1332-76-9 / 1332-76-9; Ammonium hexachloroplatinate (IV), (full information in **Annex II**). **Reference** **Bunger J. et al. 1996**

methylmethanesulfonate Positive control substance(s): 2-aminofluorene according to guideline Revised test protocol of Maron and Ames (1983) ; equivalent or similar to guideline OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	vehicle controls valid: valid negative controls valid: positive controls valid:	
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 [bacteria] (with and without met. act.) S. typhimurium TA 1538 [bacteria] (with and without met. act.) Test concentrations: 0.16, 0.8, 1.6, 4, 8, 20, 40, 100, 200 and/or 1000 µg/plate Positive control substance(s): 2-nitrofluorene Positive control substance(s): 9-aminoacridine Positive control substance(s): 2-aminofluorene; 2-aminoanthracene; N-methyl-N'-nitro-N-nitrosoguanidine according to guideline Procedures developed by Ames et al. (1975) ; equivalent or similar to guideline OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	Test results: ambiguous for S. typhimurium TA 98 [bacteria]; met. act.: with genotoxicity: ambiguous cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid: valid Test results: negative for S. typhimurium TA 98 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid: valid Test results: negative for S. typhimurium, other: TA 1537; TA 100 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid: valid Test results: negative for S. typhimurium, other: TA 1538; 1535 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	2 (reliable with restrictions) weight of evidence experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, (full information in **Annex II**). **Reference** **Bootman J and May K 1980**
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 [bacteria] (without met. act.) S. typhimurium TA 1538 [bacteria]	Test results: negative for S. typhimurium, other: Strains TA1537, TA1538 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: not specified vehicle controls valid: negative controls valid:	3 (not reliable) weight of evidence experimental study **Test material** (NH4)2PtCl6; Ammonium hexachloroplatinate,

(without met. act.) E. coli, other: B/r WP2 try- and WP2 hcr- try- [bacteria] (without met. act.) Test concentrations: Between 0.001M and 10 M. Actual test concentration(s) not reported. Positive control substance(s): no guideline followed The spot test, first described by Iyer and Sybalsky (1958) and later by Ames et al. (1975).	positive controls valid: Test results: "Not conclusive" for S. typhimurium, other: Strains TA100, TA1535 [bacteria]; met. act.: without genotoxicity: "Not conclusive" cytotoxicity: not specified vehicle controls valid: negative controls valid: positive controls valid: Test results: positive for S. typhimurium TA 98 [bacteria]; met. act.: without genotoxicity: positive cytotoxicity: not specified vehicle controls valid: negative controls valid: positive controls valid: Test results: negative for E. coli, other: Strain B/r WP2 try- [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: not specified vehicle controls valid: negative controls valid: positive controls valid: Test results: positive for E. coli, other: Strain WP2 hcr- try- [bacteria]; met. act.: without genotoxicity: positive cytotoxicity: not specified vehicle controls valid: negative controls valid: positive controls valid:	(full information in **Annex II**). **Reference** **Kanematsu N et al. 1980**
SOS/umu assay [in vitro DNA damage and/or repair study] (in vitro DNA damage and/or repair study - Type of genotoxicity: DNA damage and/or repair) E. coli, other: PQ37 [bacteria] (without met. act.) Test concentrations: Dose range was 11-367 µM Positive control substance(s): 4-nitroquinoline-N-oxide non-standard method as described by Quillardet P and Hofnung M (1985) Mut Res 147, 65-78 Bacterial SOS chromotest for DNA damage	Test results: negative for E. coli, other: PQ37 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity - Cytotoxicity threshold was 92 µM (the highest non-toxic substance concentration that was tested (ap activity >50%)). vehicle controls valid: negative controls valid: positive controls valid:	2 (reliable with restrictions) weight of evidence experimental study **Test material** Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Gebel T et al. 1997**

SOS/umu assay [in vitro DNA damage and/or repair study] (in vitro DNA damage and/or repair study - Type of genotoxicity: DNA damage and/or repair) E. coli, other: PQ37 [bacteria] (without met. act.) Test concentrations: Dose range was 11-367 µM Positive control substance(s): 4-nitroquinoline-N-oxide non-standard method as described by Quillardet P and Hofnung M (1985) Mut Res 147, 65-78 Bacterial SOS chromotest for DNA damage	Test results: negative for E. coli, other: PQ37 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity - Cytotoxicity threshold was 92 µM (the highest non-toxic substance concentration that was tested (ap activity >50%)). vehicle controls valid: negative controls valid: positive controls valid:	2 (reliable with restrictions) weight of evidence Read-across from study conducted on a member of the “hexachloroplatinate (IV) compounds” category, dipotassium hexachloroplatinate **Test material** Diammonium hexachloroplatinate, (full information in **Annex II**). **Reference** **Gebel T et al. 1997**
Justification for type of information: Dipotassium hexachloroplatinate is considered to fall within the scope of the read-across category “hexachloroplatinate(IV) compounds”. See section 13 in IUCLID for full read-across justification report.		
SOS/umu assay [in vitro DNA damage and/or repair study] (in vitro DNA damage and/or repair study - Type of genotoxicity: DNA damage and/or repair) E. coli, other: PQ37 [bacteria] (without met. act.) Test concentrations: 11-367 µM Positive control substance(s): 4-nitroquinoline-N-oxide according to guideline non standard method as described by Quillardet P and Hofnung M (1985) Mut Res 147, 65-78 Bacterial SOS chromotest for DNA damage in the strain Escherichia coli PQ37	Test results: negative for E. coli, other: PQ37 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity - Cytotoxicity reported at 92 µM vehicle controls valid: not specified negative controls valid: positive controls valid:	2 (reliable with restrictions) weight of evidence experimental study **Test material** dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3, (full information in **Annex II**). **Reference** **Lantzsch H & Gebel T 1997**
SOS/umu assay [in vitro DNA damage and/or repair study] (in vitro DNA damage and/or repair study - Type of genotoxicity: DNA damage and/or repair) E. coli, other: PQ37 [bacteria] (without met. act.) Test concentrations: 11-367 µM Positive control substance(s): 4-nitroquinoline-N-oxide according to guideline non standard method as described by Quillardet P and Hofnung M (1985) Mut Res 147, 65-78 Bacterial SOS chromotest for DNA damage in the strain Escherichia coli PQ37	Test results: negative for E. coli, other: PQ37 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity - Cytotoxicity reported at 92 µM vehicle controls valid: not specified negative controls valid: positive controls valid:	2 (reliable with restrictions) weight of evidence Read-across from study conducted on a member of the “hexachloroplatinate (IV) compounds” category, dipotassium hexachloroplatinate **Test material** Diammonium hexachloroplatinate, (full information in **Annex II**).

		Reference **Lantzsch H & Gebel T 1997**
Justification for type of information: Dipotassium hexachloroplatinate is considered to fall within the scope of the read-across category "hexachloroplatinate(IV) compounds". See section 13 in IUCLID for full read-across justification report.		
Bacillus subtilis recombination assay [in vitro DNA damage and/or repair study] (in vitro DNA damage and/or repair study - Type of genotoxicity: DNA damage and/or repair) bacteria, other: Bacillus subtilis strains H17 (Rec+, arg- try-) and M45 (Rec-, arg- try-) [bacteria] (without met. act.) Test concentrations: Between 5 and 500 mM. It is not clear whether multiple concentrations were tested; results are reported for only a single test concentration (100 mM). Positive control substance(s): no guideline available Rec assay, with cold incubation as described by Kada et al. (1972). Test for differential growth inhibition of repair, as a measure of potential DNA damage.	Test results: positive for bacteria, other: Bacillus subtilis strains H17 (Rec+, arg-try-) and M45 (Rec-, arg-try-) [bacteria]; met. act.: without genotoxicity: positive cytotoxicity: not specified vehicle controls valid: negative controls valid: positive controls valid:	4 (not assignable) weight of evidence experimental study **Test material** (NH4)2PtCl6; Ammonium hexachloroplatinate, (full information in **Annex II**). **Reference** **Kanematsu N et al. 1980**

5.7.1.2. In vivo data

The results of in vivo genotoxicity studies are summarised in the following table:

Table 5.10. In vivo genotoxicity studies

Method	Results	Remarks
mammalian erythrocyte micronucleus test [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus] in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus rat (Wistar [rat]) male oral: gavage 37.5mg/kg bw/day (actual dose received) 75mg/kg bw/day (actual dose received) 150mg/kg bw/day (actual dose received) Test item-related mortality was observed in a preliminary dose range finding study in which three male and three female rats received three consecutive daily doses of 200 mg/kg bw, and one animal of each sex received 300 mg/kg bw/day. Clinical	Genotoxicity: negative (male) toxicity: yes - One high-dose animal died after the first dose, and was replaced by an additional animal. Clinical signs of toxicity were observed in the high-dose group: hunched posture (4/5 animals), lethargy (5/5 animals) and diarrhoea (1/5 animals). vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Eurlings IMJ 2020**

signs of toxicity (ataxia, lethargy, hunched posture, rough coat and diarrhoea) were observed at 150 mg/kg bw/day, which was determined to be the maximum tolerated dose. Cyclophosphamide. - Route of administration: Gavage. - Doses / concentrations: A single dose of 19 mg/kg bw, dissolved in physiological saline. according to guideline OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus]		
mammalian comet assay [in vivo mammalian cell study: DNA damage and/or repair] in vivo mammalian cell study: DNA damage and/or repair rat (Wistar [rat]) male oral: gavage 37.5mg/kg bw/day (actual dose received) 75mg/kg bw/day (actual dose received) 150mg/kg bw/day (actual dose received) Test item-related mortality was observed in a preliminary dose range finding study in which three male and three female rats received three consecutive daily doses of 200 mg/kg bw, and one animal of each sex received 300 mg/kg bw/day. Clinical signs of toxicity (ataxia, lethargy, hunched posture, rough coat and diarrhoea) were observed at 150 mg/kg bw/day, which was determined to be the maximum tolerated dose. Ethyl methanesulphonate. - Route of administration: Gavage. - Doses / concentrations: 200 mg/kg bw, dissolved in physiological saline, administered twice. according to guideline OECD Guideline 489 (In vivo Mammalian Alkaline Comet Assay) [in vivo mammalian cell study: DNA damage and/or repair]	Genotoxicity: negative - Kidney: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Liver: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Glandular stomach: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Duodenum: no statistically significant increase in % tail intensity. cfr table under section 'Any other information on results incl. tables' (male) toxicity: yes vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Eurlings IMJ 2020**

5.7.2. Human information

No relevant information available.

5.7.3. Summary and discussion of mutagenicity

The following information is taken into account for any hazard / risk assessment (genetic toxicity in vitro):

Ammonium hexachloroplatinate was mutagenic in a bacterial reverse mutation (Ames) assay using four Salmonella typhimurium strains (TA97a, TA98, TA100 and TA102) when tested in the presence and absence of S9 (Bunger et al., 1996).

However, in a previously conducted Ames assay, ammonium hexachloroplatinate displayed no evidence of mutagenicity in S. typhimurium strains TA100, TA1535, TA1537 or TA1538 when tested at up to cytotoxic levels in the presence (TA100 and TA1537 only) or absence (all four strains) of S9. An inconsistent, weak positive result was seen in S. typhimurium TA98 in the presence, but not in the absence, of S9 (Bootman and May, 1980).

In a well-conducted in vitro mammalian gene mutation test using CHO cells, dipotassium hexachloroplatinate was weakly mutagenic when tested up to cytotoxic concentrations, in the absence of metabolic activation (Taylor et al., 1979).

Dipotassium hexachloroplatinate did not induce micronuclei in the cytokinesis-block micronucleus test with human lymphocytes, when tested at up to cytotoxic concentrations (Gebel et al., 1997).

However, according to a brief abstract, diammonium hexachloroplatinate was said to have shown a clear mutagenic effect, as indicated by the induction of a statistically higher number of micronuclei (MN) in two male donors than in controls in the dose-ranges of 75 -125 µM Pt. FISH analysis did not show a significant increase of MN-C (as a percentage), suggesting that the metal acts with both clastogenic and aneuploidogenic mechanisms (Migliore et al., 1999).

Value used for CSA (genetic toxicity in vitro): Genetic toxicity: adverse effect observed (positive)
The following information is taken into account for any hazard / risk assessment (genetic toxicity in vivo):

The in vivo genotoxicity of diammonium hexachloroplatinate, as evaluated by its ability to induce micronuclei in polychromatic erythrocytes and to cause DNA damage, was assessed in a combined study following OECD 474 and 489 and according to GLP. Male Wistar rats (5/group) were given gavage doses of 37.5, 75 or 150 mg/kg bw/day of the test item on three consecutive days, or a vehicle control. The highest-tested dose was limited by clinical signs of toxicity, including mortalities, observed in a dose range finding study. Comet analyses were conducted on preparations of liver, glandular stomach, duodenum and kidney tissues and micronuclei were analysed in bone marrow cells.

There was no increase in the number of micronucleated polychromatic erythrocytes in any treatment group. There was no increase in % tail intensity in the liver, kidney, glandular stomach or duodenum, indicating that the test item was not genotoxic to these tissues. As such, and as platinum was detected in the plasma of the test animals, diammonium hexachloroplatinate was concluded to be non-genotoxic in vivo.

Value used for CSA (genetic toxicity in vivo): Genetic toxicity: no adverse effect observed (negative)

Justification for classification or non classification

Based on the existing data set, diammonium hexachloroplatinate does not currently meet the criteria for classification as a germ cell mutagen (category 1A/1B or 2) under EU CLP criteria (EC 1272/2008).

Relevant studies: Genetic toxicity in vivo, comet (KEY) - Eurlings (2020)
Relevant studies: Genetic toxicity in vivo, micronucleus (KEY) - Eurlings (2020)
Additional information:

Ammonium hexachloroplatinate was assessed for mutagenic activity in a bacterial reverse mutation

(Ames) assay, similar to OECD Test Guideline 471, using Salmonella typhimurium strains TA97a, TA98, TA100 and TA102 and tested at up to 500 µg/plate in the presence and absence of a metabolic activation system (S9) derived from phenobarbital- and beta-naphthoflavone-induced rat livers. (It is not clear whether the di- or mono-ammonium form was used; the recommended strain TA1535 was omitted.) Mutagenic effects were seen in all four strains both in the presence and absence of metabolic activation. Although no cytotoxicity data were provided for the test material, the minimum toxic dose for the platinum salts was apparently 100 µg/plate (Bunger et al., 1996). This study conforms to OECD guidelines, aside from the lack of inclusion of a fifth tester strain.

In a previously conducted study, the mutagenic activity of ammonium hexachloroplatinate in S. typhimurium was investigated in an Ames assay, similar to OECD Test Guideline 471, using pour-plate assays. The bacterial strains employed are capable of detecting both induced frameshift (TA1537, TA1538, and TA98) and base-pair substitution (TA1535 and TA100) mutations. Tests with strains TA98, TA100 and TA1537 were conducted at least in duplicate with the test material dissolved in deionised water at up to 1000 µg/plate (and in a subsequent test, due to inhibition of growth seen at the higher levels, at up to 100 µg/plate), both with and without S9. Two further tests (both in duplicate) were conducted in all five strains in the absence of S9, with the test material dissolved in isotonic saline solution at up to 100 µg/plate. No evidence of mutagenic activity was seen in any test with strains TA1535, TA1537, TA1538 or TA100, at up to cytotoxic levels, in the absence or presence of S9 (when used). A doubling of revertant colonies (weak positive) was seen in strain TA98 using the test material in deionised water at 40 µg/plate (test 1), and 4 and 20 µg/plate (test 2), in the presence of S9, but not in its absence. A further test with TA98 (test 3), again at up to 100 µg/plate (cytotoxic level), found no doubling in revertant colonies compared to spontaneous vehicle controls, with or without S9. Therefore, the study authors concluded that "no consistent evidence was obtained of mutagenic activity with strain TA98" (Bootman and May, 1980). This study does not entirely conform to current OECD guidelines which recommend including a bacterial strain which is susceptible to oxidative mutagenesis or cross-linking agents, for example S. typhimurium TA102, or Escherichia coli WP2 uvrA. Also, where the test material was dissolved in saline, no S9 was used, which is contrary to the OECD guidelines that recommend exposing bacteria to the test substance in the presence and absence of an appropriate metabolic activation system.

In a limited Ames spot test, diammonium hexachloroplatinate induced reverse mutations in S. typhimurium strain TA98 and E. coli strain WP2 hcr- try- when tested at up to 10 mM in the absence of metabolic activation (Kanematsu et al., 1980).

Dipotassium hexachloroplatinate was tested for genotoxicity in an in vitro mammalian gene mutation test using Chinese Hamster Ovary (CHO) cells deficient in HPRT (hypoxanthine-guanine phosphoribosyl transferase).

Cells were tested only in the absence of a metabolic activation system. A 2-3-fold increase in the 8-AGR mutant frequency versus the spontaneous control was seen upon repeated subculture [prolonged exposure] with a non-cytotoxic concentration of 10 µM. This increase was apparent after 10 population doublings; the trend towards it was observed at 5 population doublings. Dipotassium hexachloroplatinate was determined to be weakly mutagenic to mammalian cells in the absence of metabolic activation under the conditions of the test (Taylor et al., 1979).

In a well-conducted study, similar to that described by OECD Test Guideline 487, the ability of dipotassium hexachloroplatinate to induce micronuclei in human peripheral mononuclear blood cells (lymphocytes) was assessed, in the absence of a metabolic activation system. The mean numbers of micronuclei in binucleate cells were 4, 5.5, 7.5 and 4 at test concentrations of 0, 5, 10 and 20 µM, respectively; there was no statistically significant change compared to the negative control. Severe cytotoxicity was observed at 40 µM. In conclusion, the test substance did not cause chromosome damage (micronuclei) in the cytokinesis-block micronucleus test with human lymphocytes (Gebel et al., 1997).

However, a brief abstract presents details of an in vitro micronucleus test using human lymphocytes from the whole blood of two young, non-smoking, males. Cells were blocked in cytokinesis by cytochalasin B. Micronuclei (MN) frequency was evaluated in binucleated lymphocytes and MN were analysed for the presence of a fluorescent signal by considering a labelled MN as centromere-positive MN (C+MN). Mytomycin (MMC, clastogen) and griseofulvin (GF, aneuploidogen) were used as positive standard mutagens. In addition, the fluorescence in situ hybridisation (FISH) technique with an alphoid centromere-specific DNA probe was applied in order to clarify the mechanism of action. Diammonium hexachloroplatinate was said to have shown a clear mutagenic effect, as indicated by the induction of a statistically higher number of MN in both donors than in controls in the dose-ranges of 75 -125 uM Pt. FISH analysis did not show a significant increase of MN-C (as a percentage), suggesting that the metal acts with both clastogenic and aneuploidogenic mechanisms (Migliore et al., 1999).

Dipotassium hexachloroplatinate did not cause DNA damage in a bacterial SOS chromotest, when tested at up to cytotoxic concentrations in the absence of metabolic activation (Gebel et al., 1997; Lantzsch and Gebel, 1997).

In a limited bacterial rec assay with ammonium hexachloroplatinate, the observed difference in inhibition of bacterial growth was described by the investigators as a strong positive rec effect, indicating possible damage DNA (Kanematsu et al., 1980).

In a combined rat micronucleus test and comet assay following OECD 474 and 489, there was no increase in the number of micronucleated polychromatic erythrocytes and no increase in % tail intensity in liver, kidney, glandular stomach or duodenum in rats given gavage doses of 37.5, 75 or 150 mg/kg bw/day of the test item on three consecutive days (Eurlings, 2020).

Several Expert Groups have assessed the toxicity profile of platinum, and various platinum compounds, including the assessment of CMR properties. All reviews have indicated that platinum compounds have been reported to be mutagenic in a range of in vitro studies (HCN, 2008; EMA, 2008; SCOEL, 2011; WHO, 1991). Cisplatin and related compounds are known DNA-reactive carcinogens and, as these compounds are better investigated due to their pharmaceutical properties, this has been confirmed in vivo. As cisplatin-type substances differ in chemical reactivity (liability of ligands, number of active sites etc.) it is reasonable to expect that not all forms of platinum are carcinogenic (HCN, 2008). Limited experimental data on carcinogenicity for other platinum compounds give no evidence of activity that would meet classification criteria (HCN, 2008;

SCOEL, 2011).

Despite the generally positive in vitro results identified for the platinum compounds in various bacterial/mammalian cell mutagenicity assays (supported by some mammalian cell cytogenicity tests), the in vivo relevance of these in vitro findings remains unclear. Indeed, the new, high-quality in vivo data showed diammonium hexachloroplatinate itself to be conclusively non -genotoxic.

References

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Detailed information on the Mode of Action is available in **Annex III.**

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

No relevant information available.

5.8.1.2. Carcinogenicity: inhalation

No relevant information available.

5.8.1.3. Carcinogenicity: dermal

No relevant information available.

5.8.1.4. Carcinogenicity: other routes

No relevant information available.

5.8.2. Human information

No relevant information available.

5.8.3. Summary and discussion of carcinogenicity

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

The results of studies on fertility are summarised in the following table:

Table 5.11. Studies on fertility

Method	Results	Remarks
rat (Crj: CD(SD) [rat]) male/female screening for reproductive / developmental toxicity - based on test type (migrated information) oral: gavage () Doses / Concentrations: 10 mg/kg bw/day Basis: actual ingested low dose Doses / Concentrations: 30 mg/kg bw/day Basis: actual ingested intermediate dose Doses / Concentrations: 100 mg/kg bw/day Basis: actual ingested high dose Vehicle: corn oil Exposure: Males were dosed from test days 1-35 (inclusive), including 2 weeks prior to mating, the mating period and approximately 2 weeks post-mating. Females were dosed from test day 1 (2 weeks prior to mating), throughout mating and gestation, until day 3 post-partum or the day before sacrifice (from test day 41 for the first sacrificed females to test day 57 for the last sacrificed female). (Once daily.) according to guideline OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	**First parental generation (P0)** NOAEL - General toxicity (PO) 30 mg/kg bw/day (actual dose received)) (male/female) based on: see 'Remark' - Two high-dose animals died prematurely (test days 8 and 23). No or reduced body weight gain and reduced food consumption was reported in high-dose males and females. Test item-related stomach and kidney lesions were reported in high-dose males and females. NOAEL - Reproductive toxicity (PO) 30 mg/kg bw/day (actual dose received)) (female) based on: Slightly increased post-implantation loss and decreased birth index were noted in the high-dose group. This was attributed to a single female with all dead implantations and 2 other females with post-implantations of 23.1% and 18.2%. **F1 generation** NOAEL : 100 mg/kg bw/day (actual dose received) (male/female) based on: No general systemic effects seen in the F1 generation at the highest tested dose **Overall reproductive toxicity** not specified Lowest effective dose / concentration Relation to other toxic effects:	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Hansen B 2015**

<u>Toxicity to reproduction: other studies</u>

No relevant information available.

5.9.1.2. Human information

No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

The results of studies on developmental toxicity are summarised in the following table:

Table 5.12. Studies on developmental toxicity

Method	Results	Remarks
rat (Crj: CD(SD) [rat]) oral: gavage () Vehicle: corn oil Exposure: Males were dosed from test days 1-35 (inclusive), including 2 weeks prior to mating, the mating period and approximately 2 weeks post-mating. Females were dosed from test day 1 (2 weeks prior to mating), throughout mating and gestation, until day 3 post-partum or the day before sacrifice (from test day 41 for the first sacrificed females to test day 57 for the last sacrificed female). (Once daily.) according to guideline OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	**Maternal animals:** NOAEL: 100 mg/kg bw/day (actual dose received) based on: (test mat.) **Fetuses:** Fetal abnormalities not specified localisation: NOAEL: 100 mg/kg bw/day (actual dose received) based on: (test mat.) **Overall developmental toxicity:** not specified Lowest effective dose / concentration: Relation to maternal toxicity:	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Hansen B 2015**

5.9.2.2. Human information

No relevant information available.

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

The following information is taken into account for any hazard / risk assessment:

In an OECD Test Guideline 421 reproduction and developmental toxicity screening study, to GLP, parental (F0) rats (12/sex/group) were administered diammonium hexachloroplatinate by oral gavage at up to 100 mg/kg bw/day for 14 days pre-mating, through mating, and (for females) throughout gestation and up to lactation day 3. Clinical signs of toxicity (including premature death, reduced body weight and growth) were observed in the high-dose groups, resulting in morphological changes to the kidneys and stomach. There was a significant increase in post-implantation loss and an accompanying decrease in birth index (although live birth index was unaffected). The study NOAEL was established to be 30 mg/kg bw/day for both systemic and reproductive toxicity (Hansen, 2015b).

Value used for CSA (route: oral):
adverse effect observed (NOAEL): 30mg/kg bw/day (subacute, rat [common rodent species])

Relevant studies: Toxicity to reproduction (KEY) - Hansen (2015b)

Relevant studies: Developmental toxicity / teratogenicity (KEY) - Hansen (2015b)

Value used for CSA (route: dermal):
no study available

Relevant studies: Toxicity to reproduction (KEY) - Hansen (2015b)

Relevant studies: Developmental toxicity / teratogenicity (KEY) - Hansen (2015b)

Value used for CSA (route: inhalation):
no study available

Relevant studies: Toxicity to reproduction (KEY) - Hansen (2015b)

Relevant studies: Developmental toxicity / teratogenicity (KEY) - Hansen (2015b)

Additional information:

No relevant data in humans were identified.

The potential of diammonium hexachloroplatinate to adversely affect the fertility and reproductive parameters of CD rats was investigated in a reproductive and developmental screening study conducted according to OECD Test Guideline 421 and to GLP. The test material (in corn oil) was administered by oral gavage. Males were dosed for 35 days (14 days pre-mating, during the mating period and for approximately 14 days post mating). Females were dosed for 14 days pre-mating, through mating, gestation and up to post-partum day 3 (test day 41-57). Three dose groups (10, 30 and 100 mg/kg bw/day) and a control group were used, each containing 12 animals of each sex. Parental (F0) animals were observed for clinical signs of toxicity throughout the study, with body weights and food consumption monitored. At necropsy, animals were subjected to external and internal macroscopic examinations for any abnormalities or pathological changes. Special attention was paid to the reproductive organs. The numbers of implantation sites and corpora lutea were recorded. Histopathological examination was performed on the ovaries, testes and epididymides of all animals in the control and high-dose groups, with special emphasis on the qualitative stages of spermatogenesis and histopathology of interstitial testicular structure. A number of reproductive indices were calculated from the collected data. Two females in the high-dose group died prematurely. Surviving high-dose animals displayed slight to extreme salivation, piloerection, and/or pale faeces were reported. Increased water consumption was observed in high-dose males. Salivation and piloerection were also observed in low- and mid-dose animals. In the high-dose group, body weights were significantly reduced compared to controls, and cellular changes to the stomach and kidneys were also reported. A significantly increased percentage post-implantation loss was reported in high-dose females, leading to a significant reduction in birth index (although live birth index was unaffected). No test item-related microscopic changes were noted in the reproductive organs at any dose level. The study NOAEL was established to be 30 mg/kg bw/day for both systemic and reproductive toxicity (Hansen, 2015b).

No reproductive toxicity studies by the inhalation or dermal route were identified, or are required.

Developmental toxicity

The following information is taken into account for any hazard / risk assessment:

In an OECD Test Guideline 421 reproduction and developmental toxicity screening study, to GLP, parental (F0) rats (12/sex/group) were administered diammonium hexachloroplatinate by gavage at 0 (corn oil), 10, 30 or 100 mg/kg bw/day. A single female with all dead implantations and two others with high post-implantation losses caused a slight increase in overall post-implantation loss and concurrent decrease in birth index, in dams at the highest tested dose. No adverse effects on reproductive parameters of parent males (F0 animals), or on developmental of offspring (FI generation), were observed at any dose, resulting in a NOAEL of 100 mg/kg bw/day (Hansen, 2015b).

Effect on developmental toxicity - development (via oral route)

Value used for CSA (route: oral):
no adverse effect observed (NOAEL): 100mg/kg bw/day (subacute; rat [common rodent species])

Relevant studies: Toxicity to reproduction (KEY) - Hansen (2015b)

Relevant studies: Developmental toxicity / teratogenicity (KEY) - Hansen (2015b)

Effect on developmental toxicity - development (via dermal route)

Value used for CSA (route: dermal):
no study available

Relevant studies: Toxicity to reproduction (KEY) - Hansen (2015b)

Relevant studies: Developmental toxicity / teratogenicity (KEY) - Hansen (2015b)

Effect on developmental toxicity - development (via inhalation route)

Value used for CSA (route: inhalation):
no study available

Relevant studies: Toxicity to reproduction (KEY) - Hansen (2015b)

Relevant studies: Developmental toxicity / teratogenicity (KEY) - Hansen (2015b)

Additional information:

No relevant data in humans were identified.

The potential of diammonium hexachloroplatinate to adversely affect the development of rats was investigated in a guideline reproductive and developmental screening study conducted according to OECD Test Guideline 421 and to GLP. The test material (in corn oil) was administered to rats by oral gavage. Males were dosed for 35 days (14 days pre-mating, during the mating period and for approximately 14 days post mating). Females were dosed for 14 days pre-mating, through mating, gestation and up to post-partum day 3 (test day 41-57). Three dose groups (10, 30 and 100 mg/kg bw/day) and a control group were used, each containing 12 animals of each sex. Parental (F0) animals were observed for clinical signs of toxicity throughout the study, with body weights and food consumption monitored. At necropsy, animals were subjected to external and internal macroscopic examinations for any abnormalities or pathological changes. Special attention was paid to the reproductive organs. Pups were carefully examined for gross abnormalities at necropsy (on post-partum day 4). Two females in the high-dose group died prematurely. Surviving high-dose animals displayed slight to extreme salivation, piloerection, and/or pale faeces were reported. Salivation and piloerection were also observed in low- and mid-dose animals. A significantly increased percentage post-implantation loss was reported in high-dose females, leading to a significant reduction in birth index (although live birth index was unaffected). No test item-related microscopic changes were noted in the reproductive organs at any dose level. There was no developmental toxicity effect (survival index, body weight, gross abnormalities) at any dose level. Consequently, the NOAEL for developmental toxicity was 100 mg/kg bw/day, the highest dose tested (Hansen, 2015b).

No developmental toxicity studies by the inhalation or dermal route were identified, or are required.

Justification for classification or non classification:

In a reliable guideline reproductive and developmental screening study with diammonium hexachloroplatinate, no adverse effects on reproductive parameters (sexual function or fertility) were seen at doses that did not also cause maternal toxicity and no microscopic effects on the reproductive organs were observed at any dose level; no adverse effects on development of offspring were apparent. As such, classification for reproductive/developmental toxicity for is not required, according to EU CLP criteria (EC 1272/2008).

Detailed information on the Mode of Action is available in **Annex III.**

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No relevant information available.

5.10.1.2. Immunotoxicity

No relevant information available.

5.10.1.3. Specific investigations: other studies

No relevant information available.

5.10.1.4. Additional toxicological effects

No relevant information available.

5.10.2. Human information

No relevant information available.

5.10.3. Summary and discussion of other effects

5.11. Derivation of DNEL(s) and other hazard conclusions

5.11.1. Overview of typical dose descriptors for all endpoints

Table 5.13. Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type
Acute toxicity	oral	adverse effect observed (LD50):

Acute toxicity	dermal	no study available
Acute toxicity	inhalation	no study available
Irritation / Corrosivity	skin	adverse effect observed (irritating)
Irritation / Corrosivity	eye	adverse effect observed (irreversible damage)
Irritation / Corrosivity	resp. tract	no study available
Sensitisation	skin	adverse effect observed (sensitising)
Sensitisation	resp. tract	adverse effect observed (sensitising)
Repeated dose toxicity	oral	adverse effect observed (NOAEL): 10mg/kg bw/day (subacute; rat [common rodent species]) Target system/organs:urinary
Repeated dose toxicity	dermal (systemic effects)	no study available
Repeated dose toxicity	dermal (local effects)	no study available
Repeated dose toxicity	inhalation (systemic effects)	no study available
Repeated dose toxicity	inhalation (local effects)	no study available
Mutagenicity	in vitro / in vivo	In vitro: adverse effect observed (positive) In vivo: no adverse effect observed (negative)
Reproductive toxicity: effects on fertility	oral	adverse effect observed (NOAEL): 30mg/kg bw/day (subacute; rat [common rodent species])
Reproductive toxicity: effects on fertility	dermal	no study available
Reproductive toxicity: effects on fertility	inhalation	no study available
Reproductive toxicity: developmental toxicity	oral	no adverse effect observed (NOAEL): 100mg/kg bw/day (subacute; rat [common rodent species])
Reproductive toxicity: developmental toxicity	dermal	no study available
Reproductive toxicity: developmental toxicity	inhalation	no study available

5.11.2. Selection of the DNEL(s) or other hazard conclusions for critical health effects

Table 5.14. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	high hazard (no threshold derived)	sensitisation (respiratory tract)
Inhalation	Systemic effects - Acute	medium hazard (no threshold derived)	acute toxicity (Oral)
Inhalation	Local effects - Long-term	high hazard (no threshold derived)	sensitisation (respiratory tract)
Inhalation	Local effects - Acute	high hazard (no threshold derived)	sensitisation (respiratory tract)
Dermal	Systemic effects - Long-term	high hazard (no threshold derived)	sensitisation (respiratory tract)
Dermal	Systemic effects - Acute	medium hazard (no threshold derived)	acute toxicity (Oral)
Dermal	Local effects - Long-term	medium hazard (no threshold derived)	sensitisation (skin)
Dermal	Local effects - Acute	medium hazard (no threshold derived)	sensitisation (skin)
Eyes	Local effects	medium hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation route: systemic effects following long-term exposure).]

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation or dermal route: systemic effects following acute exposure).]

Inhalation Local effects - Long-term

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation route: local effects following long-term or acute exposure).]

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation route: local effects following long-term or acute exposure).]

Dermal Systemic effects - Long-term

Further explanation on hazard conclusions:

[See discussion section (Hazard via dermal route: systemic effects following long-term exposure).]

Dermal Systemic effects - Acute

Further explanation on hazard conclusions:

[See discussion section (Hazard via inhalation or dermal route: systemic effects following acute exposure).]

Dermal Local effects - Long-term

Further explanation on hazard conclusions:

[See discussion section (Hazard via dermal route: local effects following long-term or acute exposure).]

Dermal Local effects - Acute

Further explanation on hazard conclusions:

[See discussion section (Hazard via dermal route: local effects following long-term or acute exposure).]

Discussion:

Hazard via inhalation route: systemic effects following long-term exposure

As no relevant data on effects of repeated inhalation exposure to diammonium hexachloroplatinate in laboratory animals are available, route-to-route extrapolation to calculate an inhalation DNEL from a reliable repeated-dose oral toxicity study was considered a suitable alternative (particularly as first pass effects are not expected to be significant for an inorganic compound). Further reassurance was gained from a reliable oral reproductive/developmental toxicity screening study, also on diammonium hexachloroplatinate.

In a guideline (OECD TG 407) 28-day gavage toxicity study, conducted according to GLP, rats (5/sex/dose) were administered diammonium hexachloroplatinate doses of 0, 10, 30 or 100 mg/kg bw/day. Males in the mid-dose group had reduced body weight and body weight gain (likely a consequence of reduced food consumption, possibly due to the local effects on the stomach), compared to controls, and mid-dose males and females were found to have lesions in the kidneys and stomach. In the high-dose group, body weights and body weight gain were affected in males and females, and lesions of the kidneys and stomach - additional to those also present in mid-dose animals - were reported. Accordingly, the NOAEL was established as 10 mg/kg bw/day (Hansen, 2015a).

In a guideline reproductive/developmental screening study (OECD TG 421), using the same gavage dose groups, high-dose parental animals displayed similar stomach and kidney lesions as those seen in the 28-day toxicity study. In this study, the NOAEL for general toxicity was set as 30 mg/kg bw/day. Females in the high-dose group also displayed slightly increased post-implantation loss and decreased birth index, although this was attributed to a single female with all dead implantations and 2 other females with high post-implantation losses. The NOAEL for fertility effects was, nevertheless, set at 30 mg/kg bw/day. There were no developmental effects seen at any dose (developmental NOAEL 100 mg/kg bw/day)(Hansen, 2015b).

Overall, the systemic NOAEL of 10 mg/kg bw/day (equivalent to 4.39 mg/kg bw/day for elemental platinum based on MWt ratios[1]) from the repeated-dose oral toxicity study was taken as the critical point of departure for calculating the long-term systemic DNEL.

Laboratory studies provide only very limited insights into the extent of absorption of platinum compounds following inhalation. When two volunteers inhaled mainly diammonium hexachloroplatinate at calculated mean air concentrations of 1.7 and 0.15 µg Pt/m3, respectively, urinary Pt concentrations peaked (15-100-fold increases were seen) about 10 hr later. The results indicated rapid absorption and urinary excretion, but gave no quantitative insights into the extent of absorption (Schierl et al., 1998). Urinary Pt measurements in rats following an acute inhalation of radiolabelled Pt, PtO2, PtCl4 or Pt(SO4)2 (particle diameter around 1 µm) indicated only small fractions of the administered dose were absorbed, even for the two soluble salts. Most of the radiolabel appeared in the faeces, presumably reflecting mucociliary clearance and a lack of significant absorption from the gastrointestinal tract (Moore et al., 1975a).

Available data indicate that absorption of soluble Pt compounds is also very low following oral exposure. In rats, less than 0.5% of an oral dose of radiolabelled PtCl4 was absorbed (Moore et al., 1975b,c). Similar results were obtained when Pt(SO4)2 was administered orally to mice (Lown et al., 1980). Following REACH guidance, the worst-case (and, therefore, most health-precautionary) scenario for DNEL calculation is obtained by considering the minimum absorption by the ‘starting’ route. Therefore, for this oral-to-inhalation extrapolation, a figure of 0.5% oral absorption has been used, taken from the laboratory study in rats. In line with the guidance, the worst-case of 100% absorption after inhalation has still been assumed for the ‘end’ route (which is clearly significantly higher than the available, albeit limited, data indicates, and thus almost certainly over-precautionary).

Corrected inhalatory NOAEC (worker, 8 h exposure/day) = oral NOAEL*(1/sRv[rat])*(ABS[oral-rat]/ABS[inh-human]) *(sRV[human]/wRV) = 10 mg/kg bw/day*(1/0.38 m3/kg bw/day)*(0.5/100)*(6.7 m3 [8h]/10 m3 [8h]) = 0.088 mg/m3

It is noted that the standard respiratory rate conversion figure (0.38 m3/kg bw/day) already incorporates a factor of 4 for allometric scaling from rat to human. An assessment factor (AF) for allometric scaling is not considered to be justified in this scenario, given that the metabolism of inorganic metal cations is conventionally assumed not to occur to any relevant extent. Moreover, ECHA guidance notes that “allometric scaling is an empirical approach for interspecies extrapolation of various kinetic processes generally applicable to substances which are renally excreted, but not to substances which are highly extracted by the liver and excreted in the bile. It appears that species differences in biliary excretion and glucuronidation are independent of caloric demand (Walton et al. 2001)” (ECHA, 2012a). Oral toxicokinetic studies have demonstrated that, while gastrointestinal absorption of platinum is very low, the absorbed fraction is excreted predominantly via the faecal route (Moore et al., 1975b). It is therefore considered appropriate to increase the corrected inhalatory NOAEC by a factor of 4.

Dose descriptor starting point (after route to route extrapolation) = Corrected inhalatory NOAEC (worker, 8 h exposure/day)*4 = 0.088*4 = 0.35 mg/m3

Application of the appropriate assessment factors (overall AF 75, described above) to this corrected inhaled NOAEC gives a systemic long-term inhalation DNEL for diammonium hexachloroplatinate of 0.0047 mg/m3 [4.7 µg/m3]. This equates to an elemental platinum exposure of 0.0021 mg/m3 [2.07 µg/m3].

Recent epidemiological studies (including Heederik et al., 2016, a retrospective cohort study of about 1040 platinum refinery workers) have provided some evidence that platinum salt sensitisation can be induced at airborne soluble platinum concentrations below 2 µg/m3. In addition, a non-guideline study demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose-dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational respiratory sensitisation/asthma. Consequently, the most appropriate and health precautionary approach was deemed to be to formulate a qualitative assessment (with ‘high hazard’ banding and recommended RMMs/OCs in Table E.3-1 of ECHA, 2012b) for systemic exposure to workers by inhalation. [For further discussion of the potential respiratory sensitisation and irritation, including that reported in recent epidemiological studies, please see the ‘Hazard via inhalation route: local effects following long-term or acute exposure’ section, below]. (It is anticipated that this qualitative approach with its associated stringent RMMs/OC requirements will also be protective for general systemic toxic effects (with due consideration of the DNEL that would be applied to the latter).

Hazard via inhalation or dermal route: systemic effects following acute exposure

DNELs for acute toxicity should be calculated if an acute toxicity hazard, leading to classification and labelling (i.e. under EU CLP regulations) has been identified and there is a potential for high peak exposures (this is only usually relevant for inhalation exposures).

There are no data in relation to acute inhalation or dermal exposure to diammonium hexachloroplatinate (or closely-related compounds). In an acute oral toxicity study in rats, an LD50 value of around 200 mg/kg bw was reported. In a range-finding phase, both rats administered 2000 mg/kg bw died, but there were no deaths at 500 mg/kg bw or below. However, when a larger group (10/sex) of animals were administered single gavage doses of 500 mg/kg bw, 4 males and 4 females died within 3 days. A subsequent group was administered 200 mg/kg bw; 4 females died from this treatment, but the remaining female and all 5 tested males survived (Middleton, 1978). On this basis, diammonium hexachloroplatinate was classified for its acute oral toxicity in category 3, according to EU CLP criteria (EC 1272/2008).

“A qualitative risk characterisation for this endpoint could be performed for substances of very high or high acute toxicity classified in Category 1, 2 and 3 according to CLP… when the data are not sufficiently robust to allow the derivation of a DNEL” (ECHA, 2012b). It is, therefore, considered suitably health precautionary to adopt the “moderate” hazard banding, and to consider the recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

Hazard via inhalation route: local effects following long-term or acute exposure

The development of allergic sensitisation following exposure to halogenated platinum compounds via the inhalation route is a well-established human health hazard associated with occupational exposure, and has been the subject of a number of comprehensive expert reviews (HCN, 2008; IPCS, 1991; Ravindraet al., 2004; SCOEL, 2011; US EPA, 2009; WHO, 2000, 2012). There is extensive epidemiological evidence (from cohort studies and case reports) that halogenated platinum salts, in particular chloroplatinates, can act as respiratory sensitisers, with exposed workers developing symptoms if the occupational levels are sufficiently high.

Asymptomatic respiratory sensitisation (detected by skin prick testing; SPT) can proceed to occupational asthma and rhinitis if exposure is continued, and such symptoms may be severe.

In most occupational studies, the individual platinum compounds involved cannot be identified because workers are unlikely to be exposed to a single platinum compound. Work by Cristaudo et al. (2005), and Linnett and Hughes (1999) indicated that the allergenic potential may be related to the degree of chlorination. Results from laboratory animal studies provide data supporting a relationship between allergenic potential and the degree of chlorination (Murdoch and Pepys, 1986, 1985, 1984a,b; Schuppe et al., 1992, 1997; WHO, 2012), and some data suggest that there is a correlation between activity and the degree of chlorination between the series of hexachloroplatinate and tetrachloroplatinate salts.

A recently-published retrospective cohort study designed to investigate platinum salt sensitisation (PSS) found a clear exposure-response relationship between chloroplatinate salts and respiratory sensitisation in workers. The study involved about 1040 refinery workers who newly joined one of five refineries during an 11-year period (1 January 2000 to 31 December 2010), and for whom a total of around 1760 personal time weighted average exposure measurements (to soluble platinum; used as a surrogate for the various chloroplatinate intermediates in particulate and liquid aerosol forms) were available. Only personal time-weighted average measurements based on the inhalable or total dust fraction, and approximating to 8-hour workshift values were included in the exposure database. Sensitisation cases were detected by SPT using a hexachloroplatinate salt, which is a method with high sensitivity and predictivity. The relationship was strongest for current (recent) and average exposure, and weaker for cumulative exposure. For current exposure categories of ≤49, >49-≤100, >100-≤252 and >252 ng/m3, Risk Ratios (RRs) were 1 (reference), 1.4, 2.2 and 3.2, respectively, the latter two values being statistically significant (p<0.005 or better). For average exposure, RRs were 1, 1.8, 4.2 and 3.0, respectively, for the ≤51.1, >51.1-≤105, >105-≤250 and >250 ng/m3 categories (all statistically significant at p<0.05 or better). The investigators concluded that “the exposure-relation for current exposure is characterized by an initial steep increase in risk starting at low exposure levels and levelling off at levels of greater than 200 ng/m3” (Heederik et al., 2016).

This recent, high-quality study is consistent with other epidemiology studies in demonstrating that PSS can be induced at estimated airborne soluble platinum concentrations (as a chloroplatinate surrogate measure) of less than 2 µg/m3 (2000 ng/m3) as an 8-hour time-weighted average value. Although the study possessed higher statistical power than any previous epidemiology investigation of PSS, due to some limitations in the low-end exposure dataset it was not possible to define a robust induction threshold (airborne critical concentration) for respiratory sensitisation to chloroplatinates.

Given the frequency of occurrence of respiratory sensitisation in workers exposed to sufficiently high occupational levels of chloroplatinates, and the severity of the symptoms that may develop, particularly if exposure is continued, the available data indicate that it is appropriate to classify diammonium hexachloroplatinate as a respiratory sensitiser, in sub-category 1A, according to EU CLP criteria. The available epidemiology data has not yet permitted delineation of an induction threshold for PSS in workplace exposure scenarios. In a recent non-guideline study, it was demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose-dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational respiratory sensitisation/asthma, further supporting the decision to formulate a qualitative assessment approach as most appropriate and health precautionary for the local effects to the respiratory tract.

It is, therefore, considered suitably health precautionary to adopt the “high” hazard banding, and to consider the recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

Hazard via dermal route: systemic effects following long-term exposure

As no relevant data on effects of repeated dermal exposure to diammonium hexachloroplatinate in humans or laboratory animals are available, route-to-route extrapolation to calculate a dermal DNEL from a reliable repeated-dose oral toxicity was considered a suitable alternative (particularly as first pass effects are not expected to be significant for an inorganic compound). Further reassurance was gained from a reliable oral reproductive/developmental toxicity screening study, also on diammonium hexachloroplatinate. These two studies have been described in detail above ["Hazard via inhalation route: systemic effects following long-term exposure"] (Hansen, 2015a,b).

The oral NOAEL of 10 mg/kg bw/day for repeated dose effects seen in the Hansen (2015a) study was taken as the health-precautionary critical point of departure for calculating the long-term systemic dermal DNEL for diammonium hexachloroplatinate. This equates to a NOAEL of 4.39 mg/kg bw/day for elemental platinum (based on MWt ratios). This point of departure is also expected to be sufficiently protective against fertility or developmental effects.

This derivation has utilised REACH guidance. In order to make the most health-precautionary derivation, the worst-case scenario is obtained by the minimum absorption by the 'starting' route. Therefore, for this oral-to-dermal extrapolation, a figure of 0.5% oral absorption has been used based on experimental data in rats (Moore, 1975b,c). The default assumption in the REACH guidance is that dermal absorption will not be higher than by the oral route (ECHA, 2012a).

However, two in vitro permeation studies on a chloroplatinate analogue, dipotassium tetrachloroplatinate, indicated a greater degree of dermal absorption [about 5-8%] than this default process would assume. Using a K2PtCl4 solution (0.3 mg Pt/ml in synthetic sweat) and full thickness skin from six donors (three African and three Caucasian), 4.8 and 2.3%, respectively (as mean values), diffused into the skin in 24 hr; the receptor solutions contained a further 3.4 and 0.5%, respectively (Franken et al., 2015). A slightly earlier publication reported mean skin diffusion and receptor solution percentages of 2.2% and 2.3%, respectively, in similar studies on full thickness skin from four Caucasian females (Franken et al., 2014). Apart from these studies, very little information appears to be available regarding dermal absorption of platinum compounds.

Furthermore, evidence of skin irritation was seen in a non-guideline patch test (Middleton, 1978), and in a skin sensitisation study (Middleton, 1977), both carried out on diammonium hexachloroplatinate. Irritation, manifesting as swelling of the ear, was also seen in a skin sensitisation test (using the mouse ear swelling test method) conducted on disodium hexachloroplatinate, a member of the "hexachloroplatinate(IV) compounds" category (Schuppe et al., 1997b). In addition, diammonium hexachloroplatinate was found to be immediately corrosive when instilled into the eyes of rabbits (Berthold, 1994), and is corrosive to metals (Harlan, 2011). As such, the possibility that diammonium hexachloroplatinate has the potential to disrupt the skin barrier (potentially facilitating dermal uptake) cannot be ruled out (despite it not being classified for skin irritation).

A high dermal bioavailability is unlikely, notably based on its high water solubility as well as experimental dermal penetration data (human in vitro studies) for a closely-related surrogate [indicating about 5-8% dermal absorption]. However, the potential of diammonium hexachloroplatinate to disrupt skin barrier function, facilitating increased dermal penetration, cannot be excluded, especially considering its known corrosivity to metals and to the eyes of rabbits. A value of 20% absorption is, therefore, proposed.

Dose descriptor starting point (after route to route extrapolation) = NOAEL*(ABS[oral-rat]/ABS[der-human]) = 10 mg/kg bw/day*(0.5%/20%) = 0.25 mg/kg bw/day.

Application of the appropriate assessment factors (overall AF 75, described above) to this corrected dermal NOAEL gives a systemic long-term dermal DNEL for diammonium hexachloroplatinate of 3.33 µg/kg bw/day, which equates to an elemental platinum exposure of 1.46 µg/kg bw/day.

However, in a recent non-guideline study, it was demonstrated that a single respiratory challenge to mice topically sensitised to ammonium hexachloroplatinate can induce dose-dependent changes in pulmonary function indicative of an allergic lung response (Williams et al., 2015). This suggests that both dermal and inhalation exposure to chloroplatinates may play a role in occupational respiratory sensitisation/asthma. As such, the most appropriate and health precautionary approach was deemed to be to formulate a qualitative assessment (with ‘high hazard’ banding and recommended RMMs/OCs in Table E.3-1 of ECHA, 2012b) for systemic exposure to workers by the dermal route. [For further discussion of the potential respiratory sensitisation and irritation, including that reported in recent epidemiological studies, please see the ‘Hazard via inhalation route: local effects following long-term or acute exposure’ section, above].

Hazard via dermal route: local effects following long-term or acute exposure

No convincing evidence of skin sensitisation was found in the only study accepted as specifically investigating this endpoint, a Guinea Pig Maximisation Test (GPMT) following a protocol considered equivalent to OECD Test Guideline 406. In the induction phase, ten females were given an intradermal injection of a saturated solution of diammonium hexachloroplatinate, followed a week later by a topical application of 50% w/w test material in petroleum jelly. Two weeks after this, a challenge topical application of 10% w/w in petroleum jelly was administered. Eight out of ten animals showed reactions 24 hours after challenge administration, but only 2/10 reactions were still observable a further 24 hours later. No reactions were seen when the animals were re-challenged a week later with lower concentrations (1 and 5%) of the test material. The study authors considered that the reactions were the result of irritation, and concluded that diammonium hexachloroplatinate was not a skin sensitiser (Middleton, 1977).

Three other available studies are relevant but might not clearly differentiate between respiratory and skin sensitisers. The first used an adaptation of the murine Local Lymph Node Assay (LLNA) method and found that cytokine levels in the lymph nodes after application of diammonium hexachloroplatinate (0.25, 0.5 or 1% in DMSO) to the ears of female mice (5/group) were comparable to those seen following testing with known respiratory (trimellitic anhydride) and skin (2,4-dinitrochlorobenzene) sensitisers (Dearman et al., 1998).

The other two studies were carried out on the structurally-related disodium hexachloroplatinate. The first used a similar protocol to the LLNA and found a 23-fold increase in the number of proliferating auricular lymph node (ALN) cells, 48 hours after application of a 5% solution in acetone to the ears of five female mice on 4 consecutive days. The response was said to be similar to that induced by the known skin sensitiser, oxazolone (Schuppe et al., 1997a). The same investigators also carried out a ‘mouse ear swelling test’ (MEST), a scientifically-acceptable study despite not following a harmonised guideline. In this study, a 5% solution of disodium hexachloroplatinate in acetone was applied to the right ear of 4-5 female mice. Challenges were applied to the left ear of the treated animals using 0.5 or 2% solutions, 6 days and 4, 8, and 20 weeks after induction. Significant increases in left ear thickness were seen in animals challenged with 2% disodium hexachloroplatinate, and the study authors concluded that the test substance was a skin sensitiser (Schuppe et al., 1997b).

The proliferative responses reported in the studies described above can be indicative of a skin or respiratory sensitisation effect. Given that reports of skin sensitisation in humans after exposure to chloroplatinate compounds (including diammonium hexachloroplatinate) are uncommon, and considering the well-documented potential for this class of compounds to cause respiratory sensitisation, it is considered that the critical hazard following exposure by the dermal route is respiratory sensitisation. Pending further investigations, it is considered suitably health-precautionary to retain the classification of diammonium hexachloroplatinate as a skin sensitiser, in sub-category 1B, according to EU CLP criteria.

According to ECHA (2012b) guidance “moderate skin sensitisers (classified in Sub-category 1B in CLP) are allocated to the moderate hazard category band on the basis that exposure to these moderate skin sensitising substances should be well-controlled”. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2012b). It should be noted that control of potential respiratory sensitisation risk via skin exposure is the predominating concern, but that the RMMs/OCs associated with the “high hazard” banding for respiratory sensitisation (as discussed in more detail, above) are considered to be sufficiently protective.

Hazard for the eyes

In a GLP study conducted according to OECD Test Guideline 405, the eye irritancy potential of diammonium hexachloroplatinate was assessed. About 90 mg (volume of about 0.1 mL) of the solid test material was instilled into the conjunctival sac of the right eye of three New Zealand white rabbits and the ocular response assessed. The severity of the corrosive effects observed caused the study investigators to sacrifice 2/3 animals after 7 days’ observation, and consequently a score for irritation index could not be calculated. In the surviving animal, marked (but reversible) irritation was seen (Berthold, 1994).

On this basis, diammonium hexachloroplatinate has been classified as causing serious eye damage (category 1), and has been allocated to the “moderate” hazard band. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

[1]MWts: Pt metal, 195.08 g mol-1; Diammonium hexachloroplatinate, 443.87 g mol-1

Table 5.15. Hazard conclusions for the general population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Inhalation	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	

Inhalation	Local effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Inhalation	Local effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Systemic effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Local effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Local effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Oral	Systemic effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Oral	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Eyes	Local effects	medium hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Inhalation Local effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Dermal Systemic effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Dermal Systemic effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Dermal Local effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Dermal Local effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Oral Systemic effects - Long-term

Further explanation on hazard conclusions:

See Discussion section

Oral Systemic effects - Acute

Further explanation on hazard conclusions:

See Discussion section

Discussion:

DNELs have been derived only for workers, not for consumers/general population. No uses have been identified in which consumers are exposed to diammonium hexachloroplatinate. In all uses with potential consumer exposure due to service life of articles, diammonium hexachloroplatinate is chemically transformed into another substance before reaching the consumers, and the subsequent lifecycle steps after this transformation are included in the assessment of the newly-formed substance. Regarding the general population, and following the criteria outlined in ECHA guidance R16 (2016), an assessment of indirect exposure of humans via the environment for diammonium hexachloroplatinate has not been performed as the registered substance is manufactured/imported/marketed at <100 tpa and is not classified as CMR.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

No relevant information available.
Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: Diammonium hexachloroplatinate (harmonised)

Related composition: Diammonium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification: data conclusive but not sufficient for classification

Name: Diammonium hexachloroplatinate

Related composition: Diammonium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification: data conclusive but not sufficient for classification

6.2. Flammability

Flammability

The available information on flammability is summarised in the following table:

Table 6.1. Information on flammability

Method	Results	Remarks
flammable solids equivalent or similar to guideline UN Manual of Tests and Criteria: Test N.1 (Test method for readily combustible solids)	Evaluation of results: not classified based on GHS criteria Study results: Flammable gasses (lower and upper explosion limits): Aerosols: Flammable solids: burning rate test: preliminary screening test (substance does not ignite and propagate combustion either by burning with flame or smouldering along 200 mm of the powder train within the 2 minutes test period) Pyrophoric solids: Pyrophoric liquid: Self-heating substances/mixtures: Substances/ mixture which in contact with water emit flammable gases: Remarks: Pile failed to ignite during the two minutes that the Bunsen flame was applied.	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Tremain SP, Atwal SS 2011**

Discussion

The following information is taken into account for any hazard / risk assessment:

Flammability
Key value for chemical safety assessment: Flammability: not classified

Diammonium hexachloroplatinate is not classified as a flammable solid in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures as the pile failed to ignite in the two minutes the Bunsen flame was applied.

Additional information:

This is a GLP compliant, guideline study considered suitable for use as the key study for this endpoint (Tremain & Atwal 2011). Diammonium hexachloroplatinate is not classified as a flammable solid in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures as it failed to ignite in the preliminary screening test.

Flash Point

No relevant information available.
Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: Diammonium hexachloroplatinate (harmonised)

Related composition: Diammonium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification (gas): data conclusive but not sufficient for classification
Classification (liquid): data conclusive but not sufficient for classification
Classification (solid): data conclusive but not sufficient for classification

Name: Diammonium hexachloroplatinate

Related composition: Diammonium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification (gas): data conclusive but not sufficient for classification
Classification (liquid): data conclusive but not sufficient for classification
Classification (solid): data conclusive but not sufficient for classification

Justification for classification or non-classification:

Based on an experimental study following UN method N1, diammonium hexachloroplatinate is not classified as a flammable solid as the pile failed to ignite in the preliminary screening test.

6.3. Oxidising potential

The available information on the oxidising potential is summarised in the following table:

Table 6.2. Information on oxidising potential

Method	Results	Remarks
oxidising solids Contact with: powdered cellulose (3 min) equivalent or similar to guideline UN Manual of Tests and Criteria: Test O.1 (Test for oxidizing solids)	Evaluation of results: GHS criteria not met Test results: Oxidising solids: 1:1 sample-to-cellulose ratio: burning rate: (mixture does not ignite and burn) 4:1 sample-to-cellulose ratio: burning rate: (mixture does not ignite and burn) Remarks:	1 (reliable without restriction) weight of evidence migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase]

	Results 3:7 (by mass) cellulose and potassium bromate reference mixture Test Number / Burning Time (seconds) / Observations: 1 / 91 / Mixture burned with an orange and greenish blue flame with some spluttering 2 / 138 / Mixture burned with an orange and blue flame with spluttering 3 / 123 / Mixture burned with an orange and blue flame with spluttering 4 / 112 / Mixture burned with an orange and blue flame with spluttering 5 / 114 / Mixture burned with an orange and blue flame	**Test material** hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full information in **Annex II**). **Reference** **Walker JA, White DF 2011**

Results	
3:7 (by mass) cellulose and potassium bromate reference mixture	

Test Number	Burning Time (seconds)	Observations
1	91	Mixture burned with an orange and greenish blue flame with some spluttering
2	138	Mixture burned with an orange and blue flame with spluttering
3	123	Mixture burned with an orange and blue flame with spluttering
4	112	Mixture burned with an orange and blue flame with spluttering
5	114	Mixture burned with an orange and blue flame

				with splluttering
	1:1 (by mass) test item and cellulose mixture			
	1	-	Grey fumes emitted: no ignition. Some charring of the mixture	
	2	-	Grey fumes emitted: no ignition. Some charring of the mixture	
	3	-	Grey fumes emitted: no ignition. Some charring of the mixture	
	4	-	Grey fumes emitted: no ignition. Some charring of the mixture	
	5	-	Grey fumes emitted: no ignition. Some charring of the mixture	

4:1 (by mass) test item and cellulose mixture		
1	-	Mixture appears to be boiling and blackening. Liquefying observed. No ignition
2	-	Mixture appears to be boiling, black liquid. Grey fumes. No ignition
3	-	Mixture appears to be boiling, black liquid. Grey fumes. No ignition
4	-	Mixture appears to be charred and melted. Grey fumes. No ignition
5	-	Mixture appears to be boiling, black liquid. Grey fumes. No ignition

Test item was fine powder but did contain some larger granules. Whole of test item was ground to a fine powder

oxidising solids Contact with: powdered cellulose (3 min) equivalent or similar to guideline UN Manual of Tests and Criteria: Test O.1 (Test for oxidizing solids)	Evaluation of results: GHS criteria not met Test results: Oxidising solids: 4:1 sample-to-cellulose ratio: burning rate: (mixture does not ignite and burn) 1:1 sample-to-cellulose ratio: burning rate: (mixture does not ignite and burn) Remarks: **Results of 3:7 (by mass) reference mixture of potassium bromate and cellulose**	1 (reliable without restriction) weight of evidence migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** 85392-65-0 / 286-924-7; Tetraammonium decachloro-mu-oxodiruthenate (4-), Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Tremain SP, Atwal SS 2011**

	Test Number	**Burning Time (s)**	**Observations**			
	1	147	An orange/blues plutteringflame which left dark grey ash			
	2	139	An orange/blues pl			

		uttering flame which left dark grey ash		
3	116	An orange/blue spluttering flame which left dark grey ash		
4	1	A		

		33	n orange/blue sputtering flame which left dark grey ash				
	5	145	An orange/blue sputtering flame which				

		left dark grey ash			

Results of 4:1 (by mass) test item and cellulose mixture

Test Number	**Burning Time (s)**	**Observations**			
1	-	P			

			ale grey smoke, no sign of ignition during the 3 minutes the power was applied
	2	-	Dark grey smoke, no si

			gn of ignition during the 3 minutes the power was applied	
	3	-	Dark grey smoke, no sign of ignition during th	

			e 3 minutes the power was applied		
	4	-	Dark grey smoke, no sign of ignition during the 3 minutes the power w		

			as applied
	5	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied
	Results of		

1:1 (by mass) test item and cellulose mixture						
1	-	Pale grey smoke, the pile was slightly charred				
2	-	Pale gr				

		ey smoke, the pile was slightly charred			
3	-	Pale grey smoke, the pile was slightly charred			
4	-	Pale grey smoke,			

		the pile was slightly charred			
5	-	Pale grey smoke, the pile was slightly charred			

The 4:1 and 1:1 test item:cellulose mixtures did not ignite and burn during the 3 minutes that the power was applied. This indicates that the test item is not an oxidising solid..

Authors state that the material, length and diameter of wire met method specifications and the appropriate combination of current and voltage was used. therefore as the physical parameters of the wire and the powere dissipation met the method specifications, the deviation from the elctrical resistance of the wire had no effect on the test.

Discussion

The following information is taken into account for any hazard / risk assessment:

Key Information:

On the basis of read-across from test results for other substances with co-ordinated chloride, in the 4+ oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid), diammonium hexachloroplatinate is not considered to be oxidising.

Value used for CSA:
Oxidising properties: no

Relevant studies: Oxidising properties WoE Read across tetraammonium decachloro-mu-oxo diruthenate - Tremain & Atwal (2011)
Relevant studies: Oxidising properties. WoE Read across hexachloroplatinic acid - Walker & White (2011)

Additional information:

The oxidising properties of diammonium hexachloroplatinate are read across from other substances with co-ordinated chloride, in the 4+ oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid). Neither of these substances are oxidising based on GLP-compliant, guideline experimental studies (Tremain & Atwal 2011, Walker & White 2011).There is also supplementary evidence that other metal chlorides are also not oxidizing. For example, other Group VIII transition metals such as cobalt (II) chloride, iron (II), iron(III) and nickel(II) chloride. Copper(I) chloride from the adjacent Group IB is also not classified for oxidizing properties, there is therefore no evidence that any transition metal chloride is an oxidant. Supplementary evidence also comes from the non-transition metal chlorides and there is no evidence from two centuries of industrial and academic experience that these substances are oxidants.

On the basis of read-across diammonium hexachloroplatinate is not classified as an oxidising solid.

Classification according to GHS

Name: Diammonium hexachloroplatinate (harmonised)

Related composition: Diammonium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification (gas): data conclusive but not sufficient for classification
Classification (liquid): data conclusive but not sufficient for classification
Classification (solid): data conclusive but not sufficient for classification

Name: Diammonium hexachloroplatinate

Related composition: Diammonium hexachloroplatinate - Registration boundary conditions (solid: particulate/powder)

Classification (gas): data conclusive but not sufficient for classification
Classification (liquid): data conclusive but not sufficient for classification
Classification (solid): data conclusive but not sufficient for classification

Justification for classification or non-classification:

On the basis of read-across from other substances with co-ordinated chloride in the 4+ oxidation state, diammonium hexachloroplatinate is not classified as an oxidising solid.

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

Additional information:

The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-). For diammonium hexachloroplatinate it was considered that the counter ion may potentially contribute to adverse effects. Therefore, for this substance limited testing was conducted on the substance itself (acute Daphnia study). The results from this study indicated that the counter ion does not lead to increased toxicity and therefore this is considered to support the assumption that toxicity is driven by the metal ion, and read across from another soluble form of the metal, in the same oxidation state, is justified for other ecotoxicity endpoints.

When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state.

Based on the available ecotoxicity data for platinum substances, it is evident that the ecotoxicity of platinum substances is not controlled by the concentration of platinum in the substance alone. It would appear that there may be a similar situation as has been observed for palladium, in that the chloride complexes may exhibit greater toxicity than complexes with other ligands. It is not, however, currently possible to identify a clear cut-off between chloro-platinum compounds and other platinum complexes, or to provide a mechanistic explanation of the effect. However, due to the observed differences in toxicity between chloride complexes and substances without chloride ligands, for platinum substances with a chloro ligand data are read across from other substances that also contain a chloro ligand.

For diammonium hexachloroplatinate, ecotoxicity data are available for the substance itself and are read across from other platinum(IV) substances that also contain a chloro ligand, hexachloroplatinic acid and platinum(IV) chloride.

7.1.1. Fish

7.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

Table 7.1. Short-term effects on fish

Method	Results	Remarks
Oncorhynchus mykiss (previous name: Salmo gairdneri) freshwater short-term toxicity to fish according to guideline OECD Guideline	LC50 (96h): 76.55 mg/L test mat. (nominal) based on: mortality (fish) (95 % Confidence Intervals: 53.89 - 108.75 mg test item/L) LC50 (96h): 25.78 mg/L element - Pt (nominal) based on: mortality (fish) (95 %	1 (reliable without restriction) key study experimental study

203 (Fish, Acute Toxicity Test) ; according to guideline EU Method C.1 (Acute Toxicity for Fish)	Confidence Interval: 18.15 - 36.63 mg Pt/L) NOEC (96h): 21 mg/L test mat. (nominal) based on: mortality (fish) NOEC (96h): 7.07 mg/L element - Pt (nominal) based on: mortality (fish) LOEC (96h): 46 mg/L test mat. (nominal) based on: mortality (fish) LOEC (96h): 15.49 mg/L element - Pt (nominal) based on: mortality (fish)	**Test material** 16941-12-1 / 241-010-7, Form: liquid (full information in **Annex II**). **Reference** **Pawlowski S and Wydra V 2005**
short-term toxicity to fish	LC50 (96h): 76.55 mg/L test mat. (nominal) based on: mortality (fish) (95 % Confidence Intervals: 53.89 - 108.75 mg test item/L) LC50 (96h): 25.78 mg/L element - Pt (nominal) based on: mortality (fish) (95 % Confidence Interval: 18.15 - 36.63 mg Pt/L) NOEC (96h): 21 mg/L test mat. (nominal) based on: mortality (fish) NOEC (96h): 7.07 mg/L element - Pt (nominal) based on: mortality (fish) LOEC (96h): 46 mg/L test mat. (nominal) based on: mortality (fish) LOEC (96h): 15.49 mg/L element - Pt (nominal) based on: mortality (fish)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** 16941-12-1 / 241-010-7, Form: liquid (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Hexachloroplatinic acid Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. Where the test results indicate that the counter ion does not lead to increased toxicity (eg for diammonium hexachloroplatinate), this is considered to support the assumption that toxicity is driven by the metal ion, and read across from another soluble form of the metal, in the same oxidation state, is justified for other ecotoxicity endpoints. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only		

carried between either substances with or substances without a chloro ligand. Data for hexachloroplatinic acid is therefore read across to dipotassium hexachloroplatinate and diammonium hexachloroplatinate, as these are all platinum (IV) substances that contain a chloro ligand. Supporting data for platinum (IV) chloride is also read across to these substances.

Discussion

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

Key Information:

For diammonium hexachloroplatinate, the ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, hexachloroplatinic acid. The 96-hour LC50 was determined to be 25.78 mg Pt L-1. The 96-hour NOEC was determined to be 7.07 mg Pt L-1.

Additional information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contain a chloro ligand, hexachloroplatinic acid.

An acute Oncorhyncus mykiss study is available for hexachloroplatinic acid following OECD guideline 203 and EU Method C.1 (Pawlowski and Wydra 2005). A static test procedure was followed. Five test concentrations were used and these were analysed using Graphite furnace-AAS method. As measured concentrations were above 100 % of the nominal values throughout the study, with a mean of 107 % of nominal, results were based on nominal concentrations. No protocol deviations were recorded. The experiment was considered to be valid because no fish died in the control and oxygen saturation was always greater than 60 %. The 96-hour LC50 was determined to be 76.55 mg test item L-1 (25.78 mg Pt L-1). The 96-hour NOEC was determined to be 21 mg test item L-1 (7.07 mg Pt L-1).

7.1.1.2. Long-term toxicity to fish

No relevant information available.

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 7.2. Short-term effects on aquatic invertebrates

Method	Results	Remarks
Daphnia magna freshwater static according to guideline OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to guideline EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 284 µg/L test mat. (nominal) based on: mortality NOEC (48h): 200 µg/L test mat. (nominal) based on: mortality EC50 (48h): 108 µg/L element (nominal) based on: mortality NOEC (48h): 76 µg/L element (nominal) based on: mortality	1 (reliable without restriction) key study experimental study **Test material** Platinate(2-), hexachloro-, diammonium; diammonium hexachloroplatinate(

		2-) / 16919-58-7 / 240-973-0, Form: solid (full information in **Annex II**). **Reference** **Simon M 2014**
Daphnia magna freshwater static according to guideline OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to guideline EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 60.8 µg/L test mat. (nominal) based on: mobility (95 % Confidence Intervals: 56.6 - 65.3 µg test item/L) NOEC (48h): 42 µg/L test mat. (nominal) based on: mobility EC50 (48h): 20.48 µg/L element - pt (nominal) based on: mobility (95 % Confidence Intervals: 19.06 - 21.99 µg Pt/L) NOEC (48h): 14.15 µg/L element - Pt (nominal) based on: mobility LOEC (48h): 62 µg/L test mat. (nominal) based on: mobility LOEC (48h): 20.88 µg/L element - Pt (nominal) based on: mobility	1 (reliable without restriction) key study experimental study **Test material** 16941-12-1 / 241-010-7, Form: liquid (full information in **Annex II**). **Reference** **Moll M and Wydra V 2005**
	EC50 (48h): 60.8 µg/L test mat. (nominal) based on: mobility (95 % Confidence Intervals: 56.6 - 65.3 µg test item/L) NOEC (48h): 42 µg/L test mat. (nominal) based on: mobility EC50 (48h): 20.48 µg/L element - pt (nominal) based on: mobility (95 % Confidence Intervals: 19.06 - 21.99 µg Pt/L) NOEC (48h): 14.15 µg/L element - Pt (nominal) based on: mobility LOEC (48h): 62 µg/L test mat. (nominal) based on: mobility LOEC (48h): 20.88 µg/L element - Pt (nominal) based on: mobility	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** 16941-12-1 / 241-010-7, Form: liquid (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Hexachloroplatinic acid Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances,		

the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. Where the test results indicate that the counter ion does not lead to increased toxicity (eg for diammonium hexachloroplatinate), this is considered to support the assumption that toxicity is driven by the metal ion, and read across from another soluble form of the metal, in the same oxidation state, is justified for other ecotoxicity endpoints. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only carried between either substances with or substances without a chloro ligand. Data for hexachloroplatinic acid is therefore read across to dipotassium hexachloroplatinate and diammonium hexachloroplatinate, as these are all platinum (IV) substances that contain a chloro ligand. Supporting data for platinum (IV) chloride is also read across to these substances.		
Daphnia magna freshwater static according to guideline OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to guideline EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 0.13 mg/L test mat. (nominal) based on: mobility (95 % Confidence Interval: 0.11 - 0.16 mg test item/L) NOEC (48h): 0.056 mg/L test mat. (nominal) based on: mobility EC50 (48h): 0.052 mg/L element - Pt (nominal) based on: mobility (95 % Confidence Interval: 0.044 - 0.064 mg Pt/L) NOEC (48h): 0.022 mg/L element - Pt (nominal) based on: mobility	1 (reliable without restriction) key study experimental study **Test material** 16941-12-1 / 241-010-7, Form: solid (full information in **Annex II**). **Reference** **Shacklady LG, Mullee DM 2001**
	EC50 (48h): 0.13 mg/L test mat. (nominal) based on: mobility (95 % Confidence Interval: 0.11 - 0.16 mg test item/L) NOEC (48h): 0.056 mg/L test mat. (nominal) based on: mobility EC50 (48h): 0.052 mg/L element - Pt (nominal) based on: mobility (95 % Confidence Interval: 0.044 - 0.064 mg Pt/L) NOEC (48h): 0.022 mg/L element - Pt (nominal) based on: mobility	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** 16941-12-1 / 241-010-7, Form: solid (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed.		

For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Hexachloroplatinic acid Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. Where the test results indicate that the counter ion does not lead to increased toxicity (eg for diammonium hexachloroplatinate), this is considered to support the assumption that toxicity is driven by the metal ion, and read across from another soluble form of the metal, in the same oxidation state, is justified for other ecotoxicity endpoints. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only carried between either substances with or substances without a chloro ligand. Data for hexachloroplatinic acid is therefore read across to dipotassium hexachloroplatinate and diammonium hexachloroplatinate, as these are all platinum (IV) substances that contain a chloro ligand. Supporting data for platinum (IV) chloride is also read across to these substances.

Discussion

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

Key Information:

The 48-hour EC50 was estimated to be 0.108 mg Pt L-1.

Additional information:

A 48 -h acute immobilisation Daphnia magna study is available for diammonium hexachloroplatinate following OECD guideline 202 and EU Method C.2 (Simon 2014). A static test system was followed. Five test concentrations were used, and fresh and aged test solutions were analysed using ICP-OES. Due to recovery rates within a range of 80 – 120 % of nominal throughout the test, nominal test item concentrations were applied for effect assessment. All validity criteria were met. The 48-hour EC50 was estimated to be 0.284 mg test item L-1 (0.108 mg Pt L-1). The 48-hour NOEC was determined to be 0.200 mg test item L-1 (0.076 mg Pt L-1).

Comparison of the EC50 value from this study with the EC50 values for another platinum(IV) substance with a chloro ligand, hexachloroplatinic acid, indicate that the results are similar when expressed as platinum concentrations, with hexachloroplatinic acid being slightly more toxic. The EC50 value for diammonium hexachloroplatinate is 0.108 mg Pt L-1, whereas the EC50 values for hexachloroplatinic acid are 0.0205 mg Pt L-1 and 0.052 mg Pt L-1. These results indicate that for diammonium hexachloroplatinate the counter ion does not appear to increase the toxicity of the test item, and read across from hexachloroplatinic acid for other ecotoxicity endpoints is appropriate, and likely to be a worst case approach.

7.1.2.2. Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 7.3. Long-term effects on aquatic invertebrates

Method	Results	Remarks
Daphnia magna freshwater long-term toxicity to aquatic invertebrates no guideline followed A standard guideline was not followed, but the study is well documented and the method used is considered to be acceptable.	NOEC (21d): 7 µg/L element - Pt (estimated) based on: reproduction (Determined as EC16/2) EC16 (21d): 14 µg/L element - Pt (not specified) based on: reproduction LC50 (21d): 520 µg/L element - Pt (not specified) based on: mortality (95% Confidence Limits: 437 - 619 µg/L) EC50 (21d): 82 µg/L element - Pt (not specified) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** Hexachloroplatinic acid, (full information in **Annex II**). **Reference** **Biesinger KE, Christensen GM 1972**
long-term toxicity to aquatic invertebrates	NOEC (21d): 7 µg/L element - Pt (estimated) based on: reproduction (Determined as EC16/2) EC16 (21d): 14 µg/L element - Pt (not specified) based on: reproduction LC50 (21d): 520 µg/L element - Pt (not specified) based on: mortality (95% Confidence Limits: 437 - 619 µg/L) EC50 (21d): 82 µg/L element - Pt (not specified) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Hexachloroplatinic acid, (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification		

takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Hexachloroplatinic acid Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. Where the test results indicate that the counter ion does not lead to increased toxicity (eg for diammonium hexachloroplatinate), this is considered to support the assumption that toxicity is driven by the metal ion, and read across from another soluble form of the metal, in the same oxidation state, is justified for other ecotoxicity endpoints. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only carried between either substances with or substances without a chloro ligand. Data for hexachloroplatinic acid is therefore read across to dipotassium hexachloroplatinate and diammonium hexachloroplatinate, as these are all platinum (IV) substances that contain a chloro ligand. Supporting data for platinum (IV) chloride is also read across to these substances.

Discussion

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC

Key Information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, hexachloroplatinic acid. The NOEC is estimated to be 7.0 µg Pt L-1.

Additional information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, hexachloroplatinic acid.

The chronic toxicity of hexachloroplatinic acid to Daphnia magna was assessed in a publication (Biesinger and Christensen 1972), where the effects of various metals on survival, growth, reproduction and metabolism of Daphnia magna were investigated. The study is acceptable with restrictions. The study does not follow a standard test guideline although the methods used are described. A semi-static test of 21 days was conducted. Twelve concentrations of the test item were used. No analytical verification of test concentrations was conducted for platinum. The 21-day LC50 of hexachloroplatinic acid for Daphnia magna was determined to be 520 µg Pt L-1. The 21-day EC50 and EC16 of hexachloroplatinic acid for the reproductive impairment of Daphnia magna were determined to be 82 µg Pt L-1, and 16 µg Pt L-1, respectively. The NOEC was not stated in the publication, but is estimated to be 7.0 µg Pt L-1, calculated by the ratio of EC16/2.

7.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 7.4. Effects on algae and aquatic plants

Method	Results	Remarks
Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) [green algae] (algae) freshwater toxicity to aquatic algae and cyanobacteria according to guideline OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006] ; according to guideline EU Method C.3 (Algal Inhibition test)	EC50 (72h): 3.925 mg/L test mat. (nominal) based on: biomass (95 % Confidence Intervals: 1.930 - 7.393 mg test item/L) EC50 (72h): 9.808 mg/L test mat. (nominal) based on: growth rate (95 % Confidence Intervals: 7.145 - 13.750 mg test item/L) NOEC (72h): 0.62 mg/L test mat. (nominal) based on: biomass EC50 (72h): 1.32 mg/L element - Pt (nominal) based on: biomass (95 % Confidence Intervals: 0.65 - 2.49 mg Pt/L) EC50 (72h): 3.3 mg/L element - Pt (nominal) based on: growth rate (95 % Confidence Intervals: 2.41 - 4.63 mg Pt/L) NOEC (72h): 0.209 mg/L element - Pt (nominal) based on: biomass NOEC (72h): 1.85 mg/L test mat. (nominal) based on: growth rate NOEC (72h): 0.623 mg/L element - Pt (nominal) based on: growth rate LOEC (72h): 1.85 mg/L test mat. (nominal) based on: biomass LOEC (72h): 0.62 mg/L element - Pt (nominal) based on: biomass LOEC (72h): 5.56 mg/L test mat. (nominal) based on: growth rate LOEC (72h): 1.87 mg/L element - Pt (nominal) based on: growth rate	1 (reliable without restriction) key study experimental study **Test material** 16941-12-1 / 241-010-7, Form: liquid (full information in **Annex II**). **Reference** **Pawlowski S and Wydra V 2005**
toxicity to aquatic algae and cyanobacteria	EC50 (72h): 3.925 mg/L test mat. (nominal) based on: biomass (95 % Confidence Intervals: 1.930 - 7.393 mg test item/L) EC50 (72h): 9.808 mg/L test mat. (nominal) based on: growth rate (95 % Confidence Intervals: 7.145 - 13.750 mg test item/L) NOEC (72h): 0.62 mg/L test mat. (nominal) based on: biomass EC50 (72h): 1.32 mg/L element - Pt (nominal) based on: biomass (95 % Confidence Intervals: 0.65 - 2.49 mg Pt/L) EC50 (72h): 3.3 mg/L element - Pt (nominal) based on: growth rate (95 % Confidence Intervals: 2.41 - 4.63 mg Pt/L) NOEC (72h): 0.209 mg/L element - Pt (nominal) based on: biomass NOEC (72h): 1.85 mg/L test mat. (nominal) based on: growth rate NOEC (72h): 0.623 mg/L element - Pt (nominal) based on: growth rate LOEC (72h): 1.85 mg/L test mat. (nominal) based on: biomass LOEC (72h): 0.62 mg/L element - Pt (nominal) based on: biomass LOEC (72h): 5.56 mg/L test mat. (nominal) based on: growth rate LOEC (72h): 1.87 mg/L element - Pt (nominal) based on: growth rate	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** 16941-12-1 / 241-010-7, Form: liquid (full information in **Annex II**). **Reference**

Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Hexachloroplatinic acid Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. Where the test results indicate that the counter ion does not lead to increased toxicity (eg for diammonium hexachloroplatinate), this is considered to support the assumption that toxicity is driven by the metal ion, and read across from another soluble form of the metal, in the same oxidation state, is justified for other ecotoxicity endpoints. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only carried between either substances with or substances without a chloro ligand. Data for hexachloroplatinic acid is therefore read across to dipotassium hexachloroplatinate and diammonium hexachloroplatinate, as these are all platinum (IV) substances that contain a chloro ligand. Supporting data for platinum (IV) chloride is also read across to these substances.		
Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) [green algae] (algae) freshwater toxicity to aquatic algae and cyanobacteria according to guideline OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006] ; according to guideline EU Method C.3 (Algal Inhibition test)	EC50 (72h): 1.3 mg/L test mat. (meas. (TWA)) based on: biomass (95% Confidence Interval: 1.1 - 1.4 mg test item/L) EC50 (72h): 2.4 mg/L test mat. (meas. (TWA)) based on: growth rate (95% Confidence Interval: 2.0 - 2.9 mg test item/L) NOEC (72h): 0.97 mg/L test mat. (meas. (TWA)) based on: not specified EC50 (72h): 0.52 mg/L element - platinum (meas. (TWA)) based on: biomass (95% Confidence Interval: 0.44 - 0.56 mg Pt/L) EC50 (72h): 0.96 mg/L element - platinum (meas. (TWA)) based on: growth rate (95% Confidence Interval: 0.8 - 1.16 mg Pt/L) NOEC (72h): 0.386 mg/L element - platinum (meas. (TWA)) based on: not specified	1 (reliable without restriction) key study experimental study **Test material** 16941-12-1 / 241-010-7, Form: solid (full information in **Annex II**). **Reference** **Mead C, Mullee DM 2001**
toxicity to aquatic algae and cyanobacteria	EC50 (72h): 1.3 mg/L test mat. (meas. (TWA)) based on: biomass (95% Confidence Interval: 1.1 - 1.4 mg test item/L)	2 (reliable with restrictions) key study read-across from

	EC50 (72h): 2.4 mg/L test mat. (meas. (TWA)) based on: growth rate (95% Confidence Interval: 2.0 - 2.9 mg test item/L) NOEC (72h): 0.97 mg/L test mat. (meas. (TWA)) based on: not specified EC50 (72h): 0.52 mg/L element - platinum (meas. (TWA)) based on: biomass (95% Confidence Interval: 0.44 - 0.56 mg Pt/L) EC50 (72h): 0.96 mg/L element - platinum (meas. (TWA)) based on: growth rate (95% Confidence Interval: 0.8 - 1.16 mg Pt/L) NOEC (72h): 0.386 mg/L element - platinum (meas. (TWA)) based on: not specified	supporting substance (structural analogue or surrogate) **Test material** 16941-12-1 / 241-010-7, Form: solid (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Hexachloroplatinic acid Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. Where the test results indicate that the counter ion does not lead to increased toxicity (eg for diammonium hexachloroplatinate), this is considered to support the assumption that toxicity is driven by the metal ion, and read across from another soluble form of the metal, in the same oxidation state, is justified for other ecotoxicity endpoints. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only carried between either substances with or substances without a chloro ligand. Data for hexachloroplatinic acid is therefore read across to dipotassium hexachloroplatinate and diammonium hexachloroplatinate, as these are all platinum (IV) substances that contain a chloro ligand. Supporting data for platinum (IV) chloride is also read across to these substances.		
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) [green algae] (algae) freshwater toxicity to aquatic algae and cyanobacteria according to guideline OECD Guideline	EC10 (72h): 0.58 µmol/L test mat. (nominal) based on: growth rate EC10 (72h): 0.24 µmol/L test mat. (nominal) based on: biomass EC20 (72h): 1.12 µmol/L test mat. (nominal) based on: growth rate EC20 (72h): 0.64 µmol/L test mat. (nominal) based on: biomass	2 (reliable with restrictions) supporting study experimental study **Test material** Platinum(IV) chloride, (full

201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test)	EC5 (72h): 0.31 µmol/L test mat. (nominal) based on: growth rate EC5 (72h): 0.04 µmol/L test mat. (nominal) based on: biomass EC10 (72h): 0.34 µmol/L element - Pt (nominal) based on: growth rate EC10 (72h): 0.14 µmol/L element - Pt (nominal) based on: biomass EC20 (72h): 0.65 µmol/L element - Pt (nominal) based on: growth rate EC20 (72h): 0.37 µmol/L element - Pt (nominal) based on: biomass EC5 (72h): 0.18 µmol/L element - Pt (nominal) based on: growth rate EC5 (72h): 0.023 µmol/L element - Pt (nominal) based on: biomass	information in **Annex II**). **Reference** **Bednarova I, Haasova V, Mikulaskova H, Nemcova B, Strakova L, Beklova M 2012**
toxicity to aquatic algae and cyanobacteria	EC10 (72h): 0.58 µmol/L test mat. (nominal) based on: growth rate EC10 (72h): 0.24 µmol/L test mat. (nominal) based on: biomass EC20 (72h): 1.12 µmol/L test mat. (nominal) based on: growth rate EC20 (72h): 0.64 µmol/L test mat. (nominal) based on: biomass EC5 (72h): 0.31 µmol/L test mat. (nominal) based on: growth rate EC5 (72h): 0.04 µmol/L test mat. (nominal) based on: biomass EC10 (72h): 0.34 µmol/L element - Pt (nominal) based on: growth rate EC10 (72h): 0.14 µmol/L element - Pt (nominal) based on: biomass EC20 (72h): 0.65 µmol/L element - Pt (nominal) based on: growth rate EC20 (72h): 0.37 µmol/L element - Pt (nominal) based on: biomass EC5 (72h): 0.18 µmol/L element - Pt (nominal) based on: growth rate EC5 (72h): 0.023 µmol/L element - Pt (nominal) based on: biomass	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Platinum (IV) chloride Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances,		

the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only carried between either substances with or substances without a chloro ligand. Data for platinum (IV) chloride is therefore read across to Diammonium hexachloroplatinate, as these are both platinum (IV) substances that contain a chloro ligand.		
Lemna minor (aquatic plants) freshwater static according to guideline OECD Guideline 221 (Lemna sp. Growth Inhibition Test)	EC50 (168h): 12.16 µmol/L test mat. (nominal) based on: growth rate (95 % Confidence interval: 9.88 - 14.44 µmol/L) EC50 (168h): 7.04 µmol/L element - Pt (nominal) based on: growth rate (95 % Confidence interval: 5.72 - 8.36) EC50 (168h): 4.096 mg/L test mat. (nominal) based on: growth rate (95 % Confidence interval: 3.33 - 4.86) EC50 (168h): 2.37 mg/L element - Pt (nominal) based on: growth rate (95 % confidence interval: 1.93 - 2.81)	2 (reliable with restrictions) supporting study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference** **Bednarova I, Mikulaskova H, Havelkova B, Strakova L, Beklova M, Sochor J, Hynek D, Adam V, Kizek R 2014**
	EC50 (168h): 12.16 µmol/L test mat. (nominal) based on: growth rate (95 % Confidence interval: 9.88 - 14.44 µmol/L) EC50 (168h): 7.04 µmol/L element - Pt (nominal) based on: growth rate (95 % Confidence interval: 5.72 - 8.36) EC50 (168h): 4.096 mg/L test mat. (nominal) based on: growth rate (95 % Confidence interval: 3.33 - 4.86) EC50 (168h): 2.37 mg/L element - Pt (nominal) based on: growth rate (95 % confidence interval: 1.93 - 2.81)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but		

there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Platinum (IV) chloride Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only carried between either substances with or substances without a chloro ligand. Data for platinum (IV) chloride is therefore read across to Diammonium hexachloroplatinate, as these are both platinum (IV) substances that contain a chloro ligand.		
Lemna minor (aquatic plants) freshwater static according to guideline OECD Guideline 221 (Lemna sp. Growth Inhibition Test)	EC50 (168h): 13.63 µmol/L test mat. (nominal) based on: biomass EC50 (168h): 19.55 µmol/L test mat. (nominal) based on: growth rate EC50 (168h): 7.89 µmol/L element - Pt (nominal) based on: biomass EC50 (168h): 11.32 µmol/L element - Pt (nominal) based on: growth rate	2 (reliable with restrictions) supporting study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference** **Bednarova I, Haasova V, Mikulaskova H, Nemcova B, Strakova L, Beklova M 2012**
	EC50 (168h): 13.63 µmol/L test mat. (nominal) based on: biomass EC50 (168h): 19.55 µmol/L test mat. (nominal) based on: growth rate EC50 (168h): 7.89 µmol/L element - Pt (nominal) based on: biomass EC50 (168h): 11.32 µmol/L element - Pt (nominal) based on: growth rate	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse		

environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Platinum (IV) chloride Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only carried between either substances with or substances without a chloro ligand. Data for platinum (IV) chloride is therefore read across to Diammonium hexachloroplatinate, as these are both platinum (IV) substances that contain a chloro ligand.

Discussion

Effects on algae / cyanobacteria

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

Key Information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from other platinum(IV) substances that also contain a chloro ligand, hexachloroplatinic acid and platinum(IV) chloride. The 72-hour EC50 for biomass and growth rate were estimated to be 1.32 mg Pt L-1 and 3.30 mg Pt L-1, respectively. The 72-hour NOEC was determined to be 0.209 mg Pt L-1 based on biomass and 0.62 mg Pt L-1 based on growth rate. The 72-hour LOEC values for biomass and growth rate were determined to be 0.62 mg Pt L-1 and 1.87 mg Pt L-1, respectively. In a second study, the 72-hour EC50 for growth rate and biomass were determined to be 0.96 mg Pt L-1 and 0.52 mg Pt L-1, respectively. The NOEC was determined to be 0.386 mg Pt L-1.

Additional information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from other platinum(IV) substances that also contain a chloro ligand, hexachloroplatinic acid and platinum(IV) chloride.

An algal growth inhibition test is available for hexachloroplatinic acid following OECD guideline 201 and EU Method C.3 (Pawlowski and Wydra 2005). A static test system was used. Five test concentrations were included and these were analysed using Graphite furnace-AAS method. The mean recovery rates were in the range 83 % to 100 % of the nominal values, apart from the sample with the highest test concentration of 50 mg L-1, where the recovery rate declined to 24 % at the end of the test. This loss was reported to be likely to be caused by centrifugation of samples. However, since the inhibition of algal growth already reached a maximal value at a lower test concentration of 25 mg L-1, results were based on nominal concentrations. No protocol deviations were recorded. All validity criteria were fulfilled. The 72-hour EC50 for biomass and growth rate were estimated to be 3.925 mg test item L-1 (1.32 mg Pt L-1) and 9.808 mg test item L-1 (3.30 mg Pt L-1), respectively. The 72-hour NOEC was determined to be 0.620 mg test item L-1(0.209 mg Pt L-1) based on biomass and 1.85 mg test item L-1 (0.62 mg Pt L-1) based on growth rate. The 72-hour LOEC values for biomass and growth rate were determined to be 1.85 mg test item L-1 (0.62 mg Pt L-1) and 5.56 mg test item L-1 (1.87 mg Pt L-1), respectively.

A second algal study was conducted with Scenedesmus subspicatus for hexachloroplatinic acid following OECD guideline 201 and EU Method C.3 (Mead and Mullee 2001). Five test concentrations were used and these were analysed using UV digestion and adsorptive stripping voltammetry. Measured test concentrations declined from 81 - 95 % to 68 - 96 % of nominal, and this decline was considered to be due to adsorption to algal cells. Results were based on time-weighted mean measured concentrations in order to give a worst case analysis of the data. The 72-hour EC50 for growth rate and biomass were determined to be 2.4 mg L-1 (0.96 mg Pt L-1) and 1.3 mg L-1 (0.52 mg Pt L-1), respectively. The NOEC was determined to be 0.97 mg L-1 (0.386 mg Pt L-1).

Data are also read across from the platinum(IV) substance platinum(IV) chloride, as supporting data. The algal growth inhibition of platinum (as platinum (IV) chloride) to Pseudokirchneriella subcapitata was assessed in the publication by Bednarova et al. (2012). The study is reliable with acceptable restrictions. It was not conducted to GLP, but followed the standard test guideline OECD 201. Five test concentrations were used. The 72-hour EC50 could not be derived. The 72-hour EC5, EC10 and EC20 values for inhibition of growth rate were determined to be 0.31, 0.58 and 1.12 µM test item (0.18, 0.34 and 0.65 µM Pt, respectively), which corresponds to 0.104, 0.195 and 0.377 mg test item L-1 (0.060, 0.113 and 0.218 mg Pt L-1, respectively). The 72-hour EC5, EC10 and EC20 values for biomass (area under the growth curve) were determined to be 0.04, 0.24 and 0.64 µM test item (0.023, 0.14 and 0.371 µM Pt, respectively), which corresponds to 0.0135, 0.081 and 0.215 mg test item L-1 (0.008, 0.047 and 0.125 mg Pt L-1).

Discussion

Effects on aquatic plants other than algae

The following information is taken into account for effects on aquatic plants other than algae for the derivation of PNEC:

Key Information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, platinum(IV) chloride. The 168-hour EC50 of platinum(IV) chloride for growth inhibition to Lemna minor was determined to be 2.372 mg Pt L-1. In a second study, the 7-d EC50 of platinum(IV) chloride for biomass (area under the growth curve) and growth inhibition to Lemna minor were determined to be 2.66 mg Pt L-1 and 3.81 mg Pt L-1, respectively.

Additional information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, platinum(IV) chloride.

The acute toxicity of platinum (as platinum (IV) chloride) to the duckweed Lemna minor was assessed in the publication by Bednarova et al. (2014). The study is reliable with acceptable restrictions. It was not conducted according to GLP and has some limitations in design or reporting, but otherwise it is adequate for assessment.

The standard test guideline OECD 221 was followed. A static test of 7 days was carried out to investigate antioxidant and enzymatic activities, alongside a microbiotest to analyse the effects of the test item to the morphology and the vegetative growth of plant colonies. Six nominal concentrations of the test item were tested. The 168-hour EC50 of platinum(IV) chloride for growth inhibition to Lemna minor was determined to be 12.16 µmol test item L-1 (7.04 µmol Pt L-1), corresponding to 4.096 mg test item L-1 (2.372 mg Pt L-1).

The toxicity of platinum (as platinum (IV) chloride) to the duckweed Lemna minor was assessed in the publication by Bednarova et al. (2012). The study is reliable with acceptable restrictions. It was not conducted according to GLP, but the standard test guideline OECD 221 was followed. A static test of 7 days was carried out to investigate the effects of the test item to the vegetative growth of exposed duckweeds. Five nominal concentrations of the test item were tested. The 7-d EC50 of platinum(IV) chloride for biomass (area under the growth curve) and growth inhibition toLemna minorwere determined to be 13.63 µM (7.89 µM Pt) and 19.55 µM (11.32 µM Pt), respectively, which corresponded to 4.59 mg test item L-1 (2.66 mg Pt L-1) and 6.59 mg test item L-1 (3.81 mg Pt L-1), respectively.

7.1.4. Sediment organisms

No relevant information available.

7.1.5. Other aquatic organisms

No relevant information available.

7.2. Terrestrial compartment

Additional information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, platinum(IV) chloride.

The chronic toxicity of platinum (as platinum (IV) chloride) to the soil invertebrate Enchytraeus crypticus was assessed in the publication by Havelkova et al. (2014). The study is reliable with acceptable restrictions, it is non-GLP, but follows OECD guideline 220. A laboratory test of 28 days with artificial soil was carried out to determine the effects of platinum on the reproduction of E. crypticus. Five nominal concentrations of the test item were included, alongside a negative control and a reference control. No significant effect on mortality was found. The 28-d EC50 of platinum(IV) chloride for inhibition of the reproduction of Enchytraeus crypticus was determined to be 161.9 µmol test item L-1(93.75 µmol Pt L-1), corresponding to 54.54 mg test item L-1 (31.58 mg Pt L-1). Only an EC50 is reported in the study, but a NOEC can be determined from the data provided in the paper. The NOEC from the study is 100 µmol test item L-1 (57.91 µmol Pt L-1), corresponding to 33.69 mg test item L-1 (19.51 mg Pt L-1). The exposures used in the study were expressed only in terms of the concentration of metal in the spiking solutions.

7.2.1. Toxicity to soil macro-organisms

The results are summarised in the following table:

Table 7.5. Effects on soil macro-organisms

Method	Results	Remarks
Enchytraeus crypticus [Annelida] (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: artificial soil	EC50 (28d): 161.9 µmol/L test mat. (nominal) based on: reproduction EC50 (28d): 93.75 µmol/L element - Pt (nominal) based on: reproduction EC50 (28d): 54.54 mg/L test mat. (nominal)	2 (reliable with restrictions) key study experimental study

according to guideline OECD Guideline 220 (Enchytraeid Reproduction Test)	based on: reproduction EC50 (28d): 31.58 mg/L element - Pt (nominal) based on: reproduction	**Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference** **Havelkova. B et al. 2014**
toxicity to soil macroorganisms except arthropods: long-term Substrate:	EC50 (28d): 161.9 µmol/L test mat. (nominal) based on: reproduction EC50 (28d): 93.75 µmol/L element - Pt (nominal) based on: reproduction EC50 (28d): 54.54 mg/L test mat. (nominal) based on: reproduction EC50 (28d): 31.58 mg/L element - Pt (nominal) based on: reproduction	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference**
Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Hexachloroplatinic acid Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. Where the test results indicate that the counter ion does not lead to increased toxicity (eg for diammonium hexachloroplatinate), this is considered to support the assumption that toxicity is driven by the metal ion, and read across from another soluble form of the metal, in the same oxidation state, is justified for other ecotoxicity endpoints. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only carried between either substances with or substances without a chloro ligand. Data for hexachloroplatinic acid is therefore read across to dipotassium hexachloroplatinate and diammonium hexachloroplatinate, as these are		

all platinum (IV) substances that contain a chloro ligand. Supporting data for platinum (IV) chloride is also read across to these substances.

Discussion of effects on soil macro-organisms except arthropods

The following information is taken into account for effects on soil macro-organisms except arthropods for the derivation of PNEC:

Key Information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, platinum(IV) chloride. The 28-d EC50 of platinum(IV) chloride for inhibition of the reproduction of Enchytraeus crypticus was determined to be 31.58 mg Pt L-1. The NOEC from the study is 19.51 mg Pt L-1.

Additional information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, platinum(IV) chloride.

The chronic toxicity of platinum (as platinum (IV) chloride) to the soil invertebrate Enchytraeus crypticus was assessed in the publication by Havelkova et al. (2014). The study is reliable with acceptable restrictions, it is non-GLP, but follows OECD guideline 220. A laboratory test of 28 days with artificial soil was carried out to determine the effects of platinum on the reproduction of E. crypticus. Five nominal concentrations of the test item were included, alongside a negative control and a reference control. No significant effect on mortality was found. The 28-d EC50 of platinum(IV) chloride for inhibition of the reproduction of Enchytraeus crypticus was determined to be 161.9 µmol test item L-1(93.75 µmol Pt L-1), corresponding to 54.54 mg test item L-1 (31.58 mg Pt L-1). Only an EC50 is reported in the study, but a NOEC can be determined from the data provided in the paper. The NOEC from the study is 100 µmol test item L-1 (57.91 µmol Pt L-1), corresponding to 33.69 mg test item L-1 (19.51 mg Pt L-1). The exposures used in the study were expressed only in terms of the concentration of metal in the spiking solutions.

7.2.2. Toxicity to terrestrial plants

No relevant information available.

7.2.3. Toxicity to soil micro-organisms

No relevant information available.

7.2.4. Toxicity to other terrestrial organisms

No relevant information available.

7.3. Atmospheric compartment

No relevant information available.

7.4. Microbiological activity in sewage treatment systems

The results are summarised in the following table:

Table 7.6. Effects on micro-organisms

Method	Results	Remarks
activated sludge of a predominantly domestic sewage freshwater static according to guideline OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to guideline EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition Test)	NOEC (3h): 3.2 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate NOEC (3h): 1.26 mg/L element - Pt (nominal) based on: inhibition of total respiration NOEC (3h): 10 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration NOEC (3h): 3.92 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration EC10 (3h): 6 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 5.5 - 6.5 mg/L) EC10 (3h): 2.35 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 2.15 - 2.55 mg/L) EC10 (3h): 8.2 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 6.0 - 11 mg/L) EC10 (3h): 3.21 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 2.35 - 4.31 mg/L) EC50 (3h): 103 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 96 - 110 mg/L) EC50 (3h): 40.33 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 37.58 - 43.065 mg/L) EC50 (3h): 83 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 76 - 91 mg/L) EC50 (3h): 32.49 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 29.75 - 35.63 mg/L)	1 (reliable without restriction) key study experimental study **Test material** Hexachloroplatinic acid, Form: Resin (full information in **Annex II**). **Reference** **Muckle M 2015**
	NOEC (3h): 3.2 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate NOEC (3h): 1.26 mg/L element - Pt (nominal) based on: inhibition of total respiration NOEC (3h): 10 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration NOEC (3h): 3.92 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration EC10 (3h): 6 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 5.5 - 6.5 mg/L)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Hexachloroplatinic acid, Form: Resin (full information in **Annex II**).

	EC10 (3h): 2.35 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 2.15 - 2.55 mg/L) EC10 (3h): 8.2 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 6.0 - 11 mg/L) EC10 (3h): 3.21 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 2.35 - 4.31 mg/L) EC50 (3h): 103 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 96 - 110 mg/L) EC50 (3h): 40.33 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 37.58 - 43.065 mg/L) EC50 (3h): 83 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 76 - 91 mg/L) EC50 (3h): 32.49 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 29.75 - 35.63 mg/L)	**Reference**

Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH The general principles applied for read across between metal substances are that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic, as is the case for many simple metals salts (e.g. anions such as SO42-, NO3-, OH-, see additional discussion below for Cl- compounds). When reading across between different metal substances, the oxidation state of the metal ion needs to be carefully considered. For metals, chemical speciation can affect both the fate of the substance in the environment and its toxicity. For some metals (e.g. chromium and arsenic), large differences in environmental toxicity between difference oxidation states have been observed. For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For platinum (IV) substances a slightly different read across approach is adopted for fulfilment of hazard endpoints and classification, compared to the approach for risk assessment. The approach for hazard data and classification takes into account potential differences in toxicity due to the co-ordinating ligands, whereas for risk assessment a worst case approach is followed in order to enable the comparison of total measured platinum(IV) concentrations in the environment with a single PNEC derived for platinum(IV) substances. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Hexachloroplatinic acid Target chemical: Diammonium hexachloroplatinate 3. ANALOGUE APPROACH JUSTIFICATION For platinum substances, the database of ecotoxicity data is not as extensive as for other metal substances, but there may be a difference in toxicity between platinum (II) and platinum (IV) substances. For this reason, read-across between different substances is limited to metal compounds in which the metal exists in the same oxidation state. Generally, the strategies applied for read across between metal substances follow the principle that ecotoxicity and the potential for adverse environmental effects are based on the metal ion in cases where the counter ions can reasonably be expected to be non-toxic. For platinum substances, in cases where the counter ion may potentially contribute to adverse effects (e.g. NH4+ or organic ligands) then limited testing has been conducted on the substance itself. Where the test results indicate that the counter ion does not lead to increased toxicity (eg for diammonium hexachloroplatinate), this is considered to support the assumption that toxicity is driven by the metal ion, and read across from another soluble form of the metal, in the same oxidation state, is justified for other ecotoxicity endpoints. There is some indication that for platinum (IV) substances, substances containing a chloro ligand are more toxic than those without a chloro ligand. As there is some evidence that platinum substances with a chloro ligand are more toxic, and this trend has been more clearly shown for other precious metal substances, read across for hazard data and classification purposes is only

carried between either substances with or substances without a chloro ligand. Data for hexachloroplatinic acid is therefore read across to dipotassium hexachloroplatinate and diammonium hexachloroplatinate, as these are all platinum (IV) substances that contain a chloro ligand. Supporting data for platinum (IV) chloride is also read across to these substances.

Discussion

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

Key Information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, hexachloroplatinic acid. The 3-h EC50, EC10 and NOEC values without ATU (nitrification inhibitor) were determined to be 40.33 mg Pt L-1, 2.35 mg Pt L-1, and 1.26 mg Pt L-1, respectively. The 3-h EC50, EC10 and NOEC values with ATU were determined to be 32.49 mg Pt L-1, 3.21 mg Pt L-1 and 3.92 mg Pt L-1, respectively.

Additional information:

For diammonium hexachloroplatinate, ecotoxicity data are read across from another platinum(IV) substance that also contains a chloro ligand, hexachloroplatinic acid.

An activated sludge respiration inhibition test was conducted with hexachloroplatinic acid following OECD guideline 209 and EU Method C.11 (Muckle 2015). Two test series were carried out, with and without the nitrification inhibitor N- allylthiourea (ATU) to discern between inhibition of nitrificators and inhibition of the total population. Based on a range-finding test where significant inhibition was observed, two additional tests were performed, where 5 concentrations ranging from 1 to 320 mg test item L-1were tested with and without ATU, respectively. A positive control was used, and all validity criteria were met. Based on nominal concentrations, the 3-h EC50, EC10 and NOEC values without ATU were determined to be 103 mg test item L-1(40.33 mg Pt L-1), 6.0 mg test item L-1(2.35 mg Pt L-1), and 3.2 mg test item L-1(1.26 mg Pt L-1), respectively. The 3-h EC50, EC10 and NOEC values with ATU were determined to be 83 mg test item L-1(32.49 mg Pt L-1), 8.2 mg test item L-1(3.21 mg Pt L-1), and 10 mg test item L-1(3.92 mg Pt L-1), respectively.

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

No relevant information available.

7.5.2. Toxicity to mammals

No relevant information available.

7.6. PNEC derivation and other hazard conclusions

7.6.1. PNEC derivation and other hazard conclusions

Table 7.7. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 0.14µg/L	Assessment factor: 50 Extrapolation method: assessment factor

	Intermittent releases: 0.205µg/L	PNEC aqua (freshwater) PNECfreshwater derived based on a NOEC of 0.007 mg Pt L-1, for Daphnia, and an assessment factor of 50. For further details see attached PNEC report
Marine water	PNEC aqua (marine water): 0.014µg/L Intermittent releases:	Assessment factor: 500 Extrapolation method: assessment factor PNEC aqua (marine water) PNEC derived based on aNOEC of 0.007 mg Pt L-1 for Daphnia and an assessment factor of 500. For further details see attached PNEC report.
Sediments (freshwater)	PNEC sediment (freshwater): 0.261mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (freshwater) PNEC derived using equilibrium partitioning based on the aquatic PNEC and a Kd value of 1862 L kg-1. For further details see attached PNEC report.
Sediments (marine water)	PNEC sediment (marine water): 0.026mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (marine water) PNEC derived using equilibrium partitioning based on the marine water PNEC and a Kd value of 1862 L kg-1. For further details see attached PNEC report.
Sewage treatment plant	PNEC STP: 0.235mg/L	Assessment factor: 10 Extrapolation method: assessment factor PNEC STP Lowest EC10 of 2.35 mg Pt L-1 from a respiration inhibition test and an assessment factor of 10
Soil	PNEC soil: 0.005mg/kg soil dw	Extrapolation method: equilibrium partitioning method PNEC soil PNEC derived using equilibrium partitioning based on the aquatic PNEC and a Kd value of 37.2 L kg-1. For further details see attached PNEC report.
Air	no hazard identified:	This substance is not expected to contribute to ozone depletion, ozone formation, global warming or acidification. Therefore, the evaluation of atmospheric risk is not required.
Secondary poisoning	insufficient hazard data available (further	All of the REACH requirements that are relevant for the

	information necessary):	tonnage band have been met for this substance. The bioaccumulation potential of the substance cannot be assessed as insufficient data are available. Screening bioaccumulation with the log Kow is not possible for this inorganic substance and bioaccumulation testing is not required for a substance registered at <100 tpa. Therefore, no conclusion on bioaccumulation potential can be made at present. This substance is classified as STOT RE Cat 1 (H372) meaning that the potential to cause toxic effects in higher organisms cannot be ruled out. However, the only use of this substance is as an industrial intermediate and stringent controls are in place to limit the occupational exposure of the substance to the workforce. These controls and risk management measures (RMMs) in place to minimise loss of an extremely high value substance also serve to severely limit any potential for environmental exposures. The STOT RE Cat 1 classification is only relevant to chloroplatinates, therefore toxic effects in higher organisms are only anticipated if the Pt remains in chloroplatinate form after treatment in RMMs (e.g. wastewater treatment) and following release to the environment and if Pt in this form is accumulated up the food chain. Although it is not possible based on current information to conclude in which form the Pt in chloroplatinate substances will exist following release to the environment there is the possibility that chloroplatinate substances may be present in another less toxic form not meeting the STOT RE Cat 1 classification anymore. The requirement for a secondary poisoning assessment cannot be ruled out based on the classification of the substance and the fact that information on bioaccumulation is lacking (although meeting the REACH data requirements), however as exposure to chloroplatinates in the environment is expected to be very limited it is unlikely that a secondary poisoning assessment will be relevant for this substance.

<u>Conclusion on environmental classification</u>

Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests. Algae and fish toxicity values are read across from hexachloroplatinic acid. The lowest acute value is a 48-hour EC50 of 0.284 mg diammonium hexachloroplatinate L-1 (0.108 mg Pt L-1) based on the short-term toxicity study on aquatic invertebrates performed with the substance itself. The lowest chronic value is a 21-day NOEC value of 0.007 mg Pt L-1 for Daphnia, based on reproduction, read across from hexachloroplatinic acid. Converting the NOEC value to a concentration of diammonium hexachloroplatinate based on molecular weight gives a NOEC of 0.016 mg diammonium hexachloroplatinate L-1. As a complete chronic dataset (fish, Daphnia and algae) is not available, classification is assessed based on both the acute and chronic data and the worst case classification assigned to the substance. Based on the acute data, an environmental classification of Acute Category 1, Chronic Category 1 is assigned to this substance. As the lowest EC50 value is $>0.1 \leq 1$ an acute M factor of 1 is assigned. A chronic M factor of 1 is also assigned, to match the acute M factor, as the classification has been determined based on acute data.

<u>General discussion</u>

Some ecotoxicity data for diammonium hexachloroplatinate is available. Data are also read across from other platinum(IV) substances with a chloro ligand, hexachloroplatinic acid and platinum(IV) chloride, in order to fulfil REACH endpoints and to determine environmental classification.

Aquatic PNECs for platinum(IV) substances are derived by pooling all available data for platinum(IV) substances and deriving the PNEC using an assessment factor approach based on the ecotoxicity data for the most toxic platinum(IV) substance as worst case. Sediment and terrestrial PNECs are derived using equilibrium partitioning.

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. PBT/vPvB criteria and justification

A PBT assessment is not required for this substance as it is inorganic.

8.1.2. Summary and overall conclusions on PBT or vPvB properties

Overall conclusion: PBT assessment does not apply.

Justification:

A PBT assessment is not required for this substance as it is inorganic.

8.2. Emission characterisation

Not relevant.

9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.0. Introduction

9.0.1. Overview of uses and Exposure Scenarios

The following table list all the exposure scenarios (ES) assessed in this CSR.

Table 1. Overview of exposure scenarios and contributing scenarios

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
ES1 - M1		Manufacture - Manufacture of the substance (as such) - Manufacture of the substance (as such) (ERC 1) - Raw material handling (PROC 1, 8b, 9, 21, 26) - Sampling/Evaluation (PROC 15) - Wet processing (PROC 1, 2, 3, 4, 5) - Separation/Filtration (PROC 1, 2, 3, 4) - Washing/Drying (PROC 1, 2, 3, 4) - Calcination (PROC 1) - Milling/Grinding/Sieving (PROC 1) - Packaging/Filling (PROC 1, 8b, 9, 21) - Cleaning and maintenance (PROC 8a, 26)	

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
ES2 - IW1	PC 19	Use at industrial site - Use as an intermediate - Use as an intermediate (ERC 6a) - Handling of medium/high dusty materials (PROC 26) - Handling of low dusty materials (PROC 26) - Handling of solutions and reaction (PROC 3, 4, 5, 8b, 9, 15) - Fully contained process (PROC 1) - Reaction process (furnace operation) (PROC 22) - Wet powder production (PROC 27a) - Hot powder production (PROC 27b) - Wet cleaning (PROC 8a) - Vacuum cleaning (PROC 26)	
Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)			

9.0.2. Introduction to the assessment

9.0.2.1. Environment

9.0.2.1.1 Regional Background Concentrations

To derive the regional background concentration for environmental compartments two approaches have been followed; EUSES modelling based on regional production volume for the aquatic environment, and data from peer-reviewed, published literature for the terrestrial compartment.

For the derivation of the regional background concentrations in the aquatic environment, the total tonnage of all platinum (Pt) compounds produced in the EU was sub-divided by region. The value input to modelling was the maximum proportion of Pt compounds produced in a single region. This regional assumption was combined with emission characteristics from the Pt manufacturing and processing sector data (Tables 1 and 2), STP removal efficiency (Section 9.0.1.1.3) and phys-chem properties to perform calculations of the regional PEC concentrations for freshwater[1]. The estimated regional background PECs were then incorporated into all GESs.

For the derivation of regional background concentrations in the terrestrial environment, data from the geochemical mapping of agricultural and grazing land soil of Europe (GEMAS)[2] project were utilised. GEMAS is a project conducted by the EuroGeoSurveys Geochemistry Expert Group and Eurometaux for the production of exposure data on metals in agricultural and grazing land soil and soil properties, at the European scale. Sampling was performed at a density of 1 site per 2500 sq. km and was completed in 2009. 2108 samples of agricultural soil (Ap-horizon, 0-20 cm, regularly ploughed fields), and 2023 samples from land under permanent grass cover (grazing land soil, 0-10 cm) were collected based on an agreed protocol[3]. For Pt, the mean concentrations for agricultural soil and grassland samples were 9.46×10^{-4} mg/kg d.w. and 9.26×10^{-4} mg/kg d.w., respectively. For these assessments, the mean for agricultural soil (9.46×10^{-4} mg/kg d.w.) was converted to a wet weight concentration (8.37×10^{-4} mg/kg w.w. based on a conversion factor of 1.13 calculated using ECHA guidance[4]) and utilised in environmental exposure assessment.

[1] The concentration in freshly deposited sediment is taken as the PEC for sediment, therefore, the properties of suspended matter are used. The concentration in bulk sediment can be derived from the corresponding water body concentration, assuming a thermodynamic partitioning equilibrium. (ECHA (2016) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 3.0, February 2016))

[2] http://gemas.geolba.ac.at/GEMAS.htm

[3] http://www.ngu.no/upload/Publikasjoner/Rapporter/2008/2008_038.pdf

[4] ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 3.0, February 2016)

9.0.2.1.2. Local PEC and tiered Risk calculation approach

Assessment has been undertaken of risks posed to all relevant environmental compartments by releases of Pt during the manufacture and downstream use of Diammonium hexachloroplatinate. Environmental risk assessment has been undertaken based on an extensive and tiered approach to derive Risk Characterisation Ratios (RCR) for all manufacturers and users in all relevant environmental compartments. The assessment initially comprised default EUSES modelling (TIER 1), following by refined modelling and use of metal-specific emission ratios (SPERCs)[5] (TIER 2) and refinements to SpERC release factors and the use of site-specific emission data (TIER 3). Measured emission data are primarily available from the Pt sector for manufacture of Pt metal and compounds and their subsequent use at the same sites as industrial intermediates. Estimation of environmental concentrations is based on algorithms taken from ECHA technical guidance[4] and risk characterisation is performed by comparison of the 'predicted environmental concentrations' (PECs) against appropriate 'predicted no effect concentrations' (PNECs) derived from ecotoxicological testing

Tier 1

The environmental modelling of the local PEC was carried out in EUSES by applying default/conservative assumptions. Default exposure scenarios covering the point source emissions to the environment from production and downstream uses of Diammonium hexachloroplatinate were created. Tier 1 local PEC calculations employed default values from the guidance based on the appropriate Environmental Release Category (ERC). Physico-chemical and fate data discussed in the previous sections of the CSR were used as input values, and the calculated PECs were compared with the PNECs derived in Section 7. If no risks were identified in any compartment or a realistic Msafe tonnage could be calculated, the environmental modelling stopped at this point.

Tier 2

The Tier 1 assessment did not, due to its conservative nature, derive RCR < 1 for most manufacturers or generate representative Msafe tonnage values for downstream user

[5] Industry Specific Environmental Release Categories (SpERCs) online at http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/

sectors. Prior to the use of site-specific or representative emission data, metal-specific environmental release categories (SpERCs) were applied (http://www.arche-consulting.be/Metal-CSA-toolbox/spercs-tool-for-metals). Again, if no risk was identified or a realistic Msafe tonnage could be calculated, the environmental modelling stopped at this point.

Tier 3

Under Tier 3 assessment, monitoring data from the Pt processing sector were applied where available (i.e. for manufacturers) or refinements were made to the release factors detailed by SpERCs on the basis of the monetary value of Pt compounds. The use of site-specific monitoring data to generate representative sector emission values resulted in RCR values of <1 for all environmental compartments for the manufacturers who also use Pt compounds as intermediates at the same sites. In the absence of site-specific or representative emission data for downstream users the release factors (RFs) detailed in the SpERCs were adjusted based on the monetary value of Pt compounds. The RFs in SpERCs are generally based on measured emissions from sites producing or using base metals such as nickel, tin and zinc. Due to the considerably higher monetary value of Pt it is considered that emissions from the manufacture and use of Diammonium hexachloroplatinate are likely to be at least an order of magnitude lower and release factors for water and air from the SpERCs have been adjusted accordingly. This is supported by the available measured data for manufacture and use as intermediates at industrial sites (ES 1 and 2), i.e. the selected release factor to water for manufacture and intermediate use of platinum compounds based on sector data (median RF of 11.9 g/T) is 168 times lower than the relevant SpERC-defined release factors (2,000 g/T based on 90P of reported site-specific release factors). Similarly, limited data on emissions to air from sites processing platinum compounds indicate a mean RF of 15.7 g/T, which is 19 times lower than the relevant SpERC value (300 g/T based on 90P from site data). An order of magnitude reduction in release estimate is therefore considered to be a reasonably conservative adjustment and emissions of Diammonium hexachloroplatinate to water and air based on RFs taken from the SpERC documents have been adjusted to 10% of the recommended value.

9.0.2.1.3 Drafting of ES

For Manufacture and Use as Intermediate at Industrial Sites

Tonnage data were collected from 14 sites and can be considered as representative for the Pt production and processing sector. An overview of the net annual amount of Pt (as metal equivalent) used per site and annual emission days to water & air given in Table 1.

The median Pt tonnage (50P) used at a single Pt production site on an annual basis is 9.2 tpa, with a 90^{th} percentile (90P) of 30 tpa. For the generic exposure scenario (GES) describing manufacture and use as an intermediate a tonnage of 30 tpa was selected, representing 90% of the sector tonnage.

Pt is emitted to the environment via the air (primarily via stack emissions) and in wastewater to the aquatic environment. An overview of the emission days per year (d/yr) to water and air is provided in Table 1. This type of information is reported for most of the sites; the median number of emission days the median number of emissions days is 330 d for water and 345 d for air. The lowest of the median values for emission days to water and air (i.e. 330 d/yr) was selected for the GES.

Table 1. Parameter values during manufacture and use as intermediate at industrial sites (ES 1.1, 1.2, 2.1 and 2.2)

Value	Site Tonnage (tpa Pt, 2012-15)	Emission days per site (d/yr)	
		Water	Air
Median (50P)	9.2	330	345
90th % Percentile (90P)	29.8	365	365
Min	-	190	240
Max	-	365	365
n	14	11	8
Selected for Exposure Scenario	30 (90P)	330 (lowest 50P)	

Lower tier modelling (i.e. Tiers 1 & 2) did not generate RCRs < 1 based on these emission characteristics so environmental exposure assessment for the manufacture of Pt substances (and their subsequent use as intermediates in further processing) was undertaken using measured emission data collected from the Pt manufacture and processing sector.

Fourteen sites involved in the production and processing of Pt substances submitted local emission and exposure information for locations in Germany, Switzerland, Belgium, Austria, the Netherlands, Italy and UK. These sites produce and process a number of different Pt compounds and it is important to note that the environment emissions cannot be allocated to a specific substance, activity or process because they are generally collected to a central treatment plant and discharged as a single discharge (e.g. emissions from wastewater treatment plant, WWTP). As a consequence, the environmental exposure estimates relate to Pt originating from the production/use of Pt metal as well as multiple Pt compounds. A sector approach rather than a substance approach is therefore taken to environmental exposure assessment for Pt.

Emissions to water

Wastewater containing Pt compounds is treated in a treatment plant (WWTP) for recovery and to prevent release to the environment. Site specific emission data were collected from the Pt manufacture and processing sector and used to calculate a release factor (RF) for use in the development of a reasonable worst case (RWC) exposure scenario. A median RF applied to a 90th percentile tonnage value is considered to give a RWC exposure scenario. Sufficient emission data were provided by 10 sites across Europe (see Table 1) that enabled the calculation of a median RF of 0.00119% (i.e. 11.9 g of Pt is released for each tonne processed, 11.9 g/T Pt).

This RF derived from sector data is considerably lower than the Kd-adjusted RF that would be recommended for Pt by the SpERC document for the manufacture of metals and metal compounds[5]. Pt has a Kd of 1862 L/kg which would give an RF of 0.2% (2000 g/T) according to the approach detailed in the SpERC document. Due to the high monetary value of Pt, emissions are minimised as much as possible leading to lower release factors than for other metals (such as those considered for the basis of the SpERCs). It may therefore be considered reasonable to adjust other metal sector SpERCs by up to an order of magnitude when considered high value metals such as platinum.

Dilution

The dilution capacity of the receiving water body (and STP where relevant) will considerably influence the PEC values for the aquatic environment. The majority of sites from the Pt manufacturing and processing sector gave information on the flow rates of the ultimate receiving water body, and the STP where relevant. Table 2 provides an overview of the flow rates and dilution capacity for STPs and receiving water bodies for ES 1: manufacture and ES 2: use as an intermediate at industrial sites. For manufacturing and downstream user scenarios where no dilution factor data were provided, default dilution factors of 10 and 100 for the freshwater and marine environment are applied, with a maximum dilution factor of 1000 applied for freshwater direct discharge exposure scenarios.

Removal of Pt in STPs

For those facilities discharging their wastewater via the sewage system the size of sewage treatment plants (STPs) and their removal efficiency for Pt will also have a significant influence on the PEC in the receiving water body. The removal of Pt in STPs was determined from a sampling programme at three sewage treatment plants (STPs) in Europe; two in Germany, and one in the United Kingdom (UK) were sampled over a 12-month period. All STPs received wastewater from Pt processing sites discharging wastewater that had been treated at on-site wastewater treatment plants (WWTPs). Based on measurements of total Pt in influent and effluent, the median removal efficiency for Pt was calculated to be 57% and this value has been used in exposure modelling as the amount of Pt partitioning to sewage sludge at STPs with the remaining 43% passing through the STP to the receiving water body[6].

Emissions to air

Airborne emissions are treated by in-stack mitigation systems prior to discharge in order to prevent atmospheric emissions and to retain Pt-rich particulates. Only a very limited amount of stack emission data were provided by sites manufacturing and processing Pt metal and compounds. The use of adjusted SpERC release factors (RFs) for emissions to air is recommended based on the available data. The release factor to air for all exposure scenarios (used to estimates soil concentrations following subsequent deposition from air) is

6 Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment. In: Abstracts Book of the SETAC Europe 26th Annual Meeting – 22-26 May 2016, Nantes, France, Society of Environmental Toxicology and Chemistry

set at 10% of the reported SpERC RF. This approach is supported by comparison of the available data to the SpERC RF for 'manufacture of metal compounds'[7]. The SpERC RF of 0.3% (equivalent to 300 g/T) is over 19x higher than the mean measured RF of 15.7 g/T based on quantifiable measurements from four sites manufacturing Pt compounds.

Table 2: Release factor and dilution capacity for discharge to aquatic environment during manufacture of Pt compounds and their use as intermediates at industrial sites (ES 1.1, 1.2, 2.1 and 2.2)

Value	Release factor (RF) (g/T)	On-site effluent flow (m^3/d)	STP flow (m^3/d)	River flow rate (m^3/d)	Dilution factor to STP	Dilution factor STP to river
Median (50P)	11.9	58.9	25000	6972480	2253	32
90P	275	450	177587	16000000	11282	641
10P	0.3	2.5	2995	51083.4	24	17
Min	0.4	3	2950	2950	19	2
Max	500	2592	1344000	16000000	22818	641
N	10	11	10	8	7	7
Selected for ES 1.1 & 2.1 Freshwater – via STP	11.9 (50P)	60 (50P)	3000 (10P STP flow rate)		50 (based on median effluent flow rate & 10P STP flow)	32 (median dilution factor)
Selected for ES 1.2 &		3000		1000 max (dilution		

[7] http://www.arche-consulting.be/content/documents/Eurometaux-1.2.v2.1.Pdf

Value	Release factor (RF) (g/T)	On-site effluent flow (m^3/d)	STP flow (m^3/d)	River flow rate (m^3/d)	Dilution factor to STP	Dilution factor STP to river
2.2 Freshwater – direct discharge to water				factor for only site with direct discharge is 4800)		

9.0.2.2. Man via environment

An assessment of indirect exposure of humans via the environment is not required as the substance is not being registered at > 100 t/y[8].

9.0.2.3. Workers

Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table based on the hazard conclusions presented in section 5.11.

[8] An assessment of indirect exposure of humans via the environment is generally only conducted if:

- the tonnage >1 000 t/y or
- the tonnage >100 t/Y and the substance is classified as STOT RE 1; or as a carcinogen or mutagen (any category); or as toxic to reproduction (categories 1A or 1B). (ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 3.0, February 2016))

Table 2. Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic, long-term	Qualitative	High hazard	Respiratory sensitisation
	Systemic, acute	Qualitative	High hazard	Based on acute oral classification
	Local, long-term	Qualitative	High hazard	Respiratory sensitisation
	Local, acute	Qualitative	High hazard	Respiratory sensitisation
Dermal	Systemic, long-term	Qualitative	High hazard	Respiratory sensitisation
	Systemic, acute	Qualitative	High hazard	Based on acute oral classification
	Local, long-term	Qualitative	Medium hazard	Skin sensitisation
	Local, acute	Qualitative	Medium hazard	Skin sensitisation
Eye	Local	Qualitative	Medium hazard	-

For the chloroplatinate (ClPt) substances, where a qualitative assessment methodology has been applied according to ECHA Guidance on Information Requirements and Chemical Safety Assessment, Part E: Risk Characterisation (ECHA, 2016), numerical exposure estimates have also been derived. However, the inhalation exposure estimate has not been directly compared to the OEL value of 2 µg/m^3 (as soluble Pt) for complex halogenated platinum salts– including chloroplatinates– which is currently in force at national level in most EU territories. This is due to reservations about the OEL's scientific robustness and whether it is fully health-protective in respect of chloroplatinate respiratory sensitisation; as addressed by an EU SCOEL assessment (SCOEL, 2011). Instead, corresponding to approaches set out in ECHA Practical Guide 15 (ECHA, 2012), expert judgement has been applied to set a benchmark value of 0.1 µg/m^3 (based on airborne soluble Pt as a surrogate measure). This benchmark value has been derived from a recently published retrospective study (Heederik et al.,2015) involving 1040 refinery workers in five different refineries over eleven year period from January 2000 to December 2010. This high quality study found a clear exposure-response relationship between chloroplatinate salts and respiratory sensitisation in workers and using a risk modelling approach based upon the 'Dutch Health Council' (1% excess risk in workplace of initiating Pt salt sensitisation) estimated that to be protective for workers the exposure level should be below 0.1 μg/m^3. Although work is continuing to refine this value it is considered to align with a categorisation of "low exposure" . As set out elsewhere in this document, calculated final personal exposure levels in the occupational ES in Section 9 of the CSR of the individual platinum substances integrate exposure reduction adjustments due to use of RPE, as relevant for each ES. Requirements for use of RPE, and the associated RPE Assigned Protection Factors (APF), have been based on control of exposure so as not to exceed the selected benchmark value. Risk characterisation statements made for the various ES are also aligned with the application of this benchmark value.

Comments on assessment approach related to toxicological hazard:

GENERAL GOOD OCCUPATIONAL HYGIENE PRACTICES

In the platinum industry, good occupational hygiene practices are followed to ensure safe handling of platinum substances. Generally, inhalation (e.g. dust should not be blown off with compressed air) and ingestion (e.g. no eating and smoking in the workplace, regular cleaning with suitable cleaning devices) must be avoided. More specific measures include:

(i) work clothing is not taken home,

(ii) good general ventilation in the workplace is always ensured,

(iii) regular training in workplace hygiene practice and proper use of personal protective equipment (where relevant).

SPECIFIC MEASURES TO MINIMISE THE RISK FOR RESPIRATORY SENSITISATION

Each contributing exposure scenarios (CES) below describes the conditions of use to ensure safe use of the substance. In addition to the described operational conditions and risk management measures in the CES at the process level and general good occupational hygiene practices as outlined above, common measures are required whenever chloroplatinates are present in a workplace. These measures include technical and organisational measures that are implemented in the platinum industry.

TECHNICAL MEASURES

- High level of containment wherever possible.
- Closed systems allow for easy maintenance.
- Wherever possible, all process systems are kept under negative pressure.
- Chloroplatinates are handled in dedicated areas.

ORGANISATIONAL MEASURES

- All machinery/systems and risk management measure are regularly tested for proper functioning.
- Training of workers in use of PPE, equipment and specifically for handling chloroplatinates.
- Training of personnel for emergency situations.
- Permits required for not-authorized personnel for entering the work area.

QUALITATIVE RISK CHARACTERISATION FOR RESPIRATORY SENSITISATION

The quantitative exposure assessment for the individual CES as reported below generally indicates very low exposure levels for the dermal and the inhalation route for chloroplatinates indicating efficient risk management measures at the process level. In addition, organisational measures ensure that any residual exposures are controlled. Contamination of adjacent workplaces is excluded by stringent housekeeping measures such as immediate and careful removal of any contamination of surfaces. It is therefore concluded that the risk for respiratory sensitisation is minimised to an extent as technical feasible by the application of all relevant state-of-the-art risk mitigation measures.

QUALITATIVE RISK CHARACTERISATION FOR OTHER EFFECTS

Due to the stringent conditions in place to protect for respiratory sensitisation any other adverse health effects that can be caused by chloroplatinates are inherently prevented.

Please refer to the document "Methodology applied in the occupational exposure scenarios for platinum substances" as annexed to the CSR for further information on the applied methodology for the occupational exposure assessment.

General information on risk management related to toxicological hazard:

GENERAL INFORMATION RELATED TO PERSONAL PROTECTIVE EQUIPMENT FOR WORKERS

Use of personal protective equipment for each of the exposure routes listed below is required as described here, unless exposure to the substance can be excluded for the respective route(s) of exposure. Such exclusion of exposure may be determined by:
(i) the physical appearance of the substance in the specific type of application (e.g. wetting the substance can effectively prevent from the emission of dust),
(ii) the emission potential resulting from the nature of the process (e.g. splashes, emission of dust can be excluded in a closed process),
(iii) applied exposure prevention measures (segregation of the emission source or separation of the worker from the emission source), and
(iv) the amount of the handled/emitted material during use in relation to the room size (i.e. dilution factor) under consideration of the prevailing air exchange rates during use.

DERMAL ROUTE (SKIN PROTECTION)

When dermal protective equipment is required, specific information is provided in the occupational exposure scenarios below. Further, dermal protective equipment is to be selected in consideration of mechanical, cold or heat stress or any other physico-chemical hazards as relevant for the conducted tasks and working environment in addition to the effectiveness of the equipment to control exposure. Certified safety clothing including coveralls and safety shoes are generally worn. Protective gloves comply with EN 374 and are changed according to manufacturer's information or when damaged, whatever is the earlier.

INHALATION ROUTE (RESPIRATORY PROTECTION)

When respiratory protective equipment (RPE) is required, specific information on the required assigned protection factor (APF) is provided in the occupational exposure scenarios below. RPE should be selected based on the given APF according to EN 529 and should comply with national legislation. If RPE has to be worn, an APF of 10 represents the required minimum level of protection.

RPE shall only be worn if the following principles are implemented in parallel: The duration of work should take into account the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself and due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.

For reasons as given above, the worker should therefore:

(i) be healthy (especially in view of medical problems that may affect the use of RPE), and

(ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair).

The devices recommended in the ES which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

The employer and self-employed persons have legal responsibilities for the maintenance and supply of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of workers.

EYE/FACE PROTECTION

Eye/face protective equipment is to be selected in consideration of mechanical, cold or heat stress or any other physico-chemical hazards as relevant for the conducted tasks and working environment in addition to the effectiveness of the equipment to control exposure.

9.0.2.4. Consumers

Exposure assessment is not applicable as there are no consumer-related uses for the substance.

9.0.2.5 Physico-chemical properties

Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.

The substance is classified as Metal corrosivity category 1, therefore do not handle until all safety precautions have been read and understood. Taking into consideration the precautionary statements all uses of the substance for all users can be considered safe regarding corrosion to metals.

9.1. Exposure scenario 1: Manufacture - Manufacture of the substance (as such)

Environment contributing scenario(s):	
Manufacture of the substance (as such)	ERC 1
Worker contributing scenario(s):	
Raw material handling	PROC 1, 8b, 9, 21, 26
Sampling/Evaluation	PROC 15
Wet processing	PROC 1, 2, 3, 4, 5
Separation/Filtration	PROC 1, 2, 3, 4
Washing/Drying	PROC 1, 2, 3, 4
Calcination	PROC 1
Milling/Grinding/Sieving	PROC 1
Packaging/Filling	PROC 1, 8b, 9, 21
Cleaning and maintenance	PROC 8a, 26

9.1.1. Environmental contributing scenario 1: Manufacture of the substance (as such)

9.1.1.1. Conditions of use

The conditions of use are as described in the generic exposure scenario (GES) below.

9.1.1.2. Releases

The GES and associated risk assessment are concerned with releases of Pt to wastewater and air arising from the manufacture of diammonium hexachloroplatinate at an industrial site.

Wastewater is treated by an on-site wastewater treatment plant (WWTP) prior to discharge to the receiving water body in a number of ways:

- To freshwater via a municipal sewage treatment plant (STP) [ES 1.1]; or
- Direct discharge to freshwater [ES 1.2];

Airborne emissions are treated by in-stack mitigation systems prior to discharge (all ES). Exposure assessment for the environment is based on representative exposure characteristics from the Pt manufacturing and processing sector for wastewater emissions and adjusted SpERC values for stack emissions to air (supported by a limited amount of emission data).

A sector-wide monitoring dataset is available, based on emissions of total Pt, resulting from production and use of a variety of Pt compounds collected during 2012 - 2016 from sites across Europe. In this assessment the release factor (RF) for wastewater is set at 0.00119 % (equivalent to 11.9 g/T); the 50^{th} percentile measured wastewater release factor from 9 sites. The use of adjusted release factors for air is supported by the available data on measured Pt emissions in air at sites producing Pt compounds. In this assessment the release factor (RF) to air is set at 10% of the SpERC RF for 'manufacture of metal compounds'[9] to air of 0.03% (adjusted from 0.3% and equivalent to 30 g/T) is much higher than the mean measured RF of 15.7 g/T based on quantifiable measurements from four sites manufacturing Pt compounds.

9.1.1.3. Risk Management Measures (RMMs)

All sites from the Pt manufacturing and processing sector that provided data on emissions to water reported that wastewater treatment was primarily based on chemical precipitation followed by sedimentation and/or filtration. Two sites reported an additional step involving ion exchange. The reported efficiency for treatment of wastewater containing Pt compounds varied from 98 to 99.99%, with the majority of sites reporting ≥ 99.9% removal efficiency. Similarly, all sites reporting on RMMs for stack emissions to air (n=3) stated the use of wet scrubbers, with reported efficiency of ≥ 99%

[9] http://www.arche-consulting.be/content/documents/Eurometaux-1.2.v2.1.pdf

9.1.1.4. Exposure Scenario

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for manufacture of diammonium hexachloroplatinate is detailed below:

1. Title **ES1: Manufacture of diammonium hexachloroplatinate**	
Life cycle	Manufacture - Manufacture of the substance (as such)
Systematic title based on use descriptor	ERC: ERC 1 Manufacture of substances
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Production of diammonium hexachloroplatinate
Systematic title based on use descriptor (environment)	ERC 1 Manufacture of substances
Processes, tasks, activities covered (environment)	Production of diammonium hexachloroplatinate: Raw material delivery and handling, production and processing of diammonium hexachloroplatinate, packaging of diammonium hexachloroplatinate, cleaning & maintenance.
Environmental Assessment Method	Estimates based on monitoring data of emissions, local and regional concentrations are used for calculation of PECs
Product characteristics Diammonium hexachloroplatinate as solid or aqueous solution.	

Environmental assessment is based on the estimated emission of diammonium hexachloroplatinate in wastewater discharge and in stack emissions to air.	
Amounts used	
Annual production/use at a site	ES 1.1 and ES 1.2: 68.3 tonnes diammonium hexachloroplatinate (30 tonnes Pt metal equivalent); 90P from sector data
Frequency and duration of use	
Pattern of release to the environment	330 days per year per site (50P from sector data)
Environment factors not influenced by risk management	
Receiving surface water flow rate	ES 1.1: STP: 3,000 m^3/d (minimum STP size from sector data) Receiving water: 93,000 m^3/d (based on 50P dilution factor from sector data) ES 1.2: Receiving water: 2,997,000 m^3/d (maximum allowable dilution factor of 1000; assumption made on knowledge of sector data.)
Dilution capacity, freshwater	ES 1.1: Discharge to freshwater via STP: DF in STP = 25; DF in receiving water = 32 (sector data) ES 1.2: Direct discharge to freshwater: DF = 1,000 (maximum allowable)
Dilution capacity, marine	Not relevent
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	

Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: All ES: On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99.9 % (sector data) Release factor after on-site treatment: 11.9 g/T (50P from sector data) ES 1.1. Off-site municipal sewage treatment plant (STP) Efficiency 57.1 % (based on European STP monitoring programme[10]) **Air:** All ES: Treatment of air emissions by wet scrubbers and filters (e.g. fabric, bag, HEPA). Release factor after on-site treatment: 30 g/T (10% of SpERC RF for 'Manufacture of metal compounds'[11])	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	
Municipal Sewage Treatment Plant (STP)	ES 1.1: Yes ES 1.2: No
Discharge rate of the Municipal STP	ES 1.1: 3 000 m^3/d (minimum from sector data)
Fate of the sludge from Municipal	The sludge is incinerated (with ash going to landfill)

[10] Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment. In: Abstracts Book of the SETAC Europe 26th Annual Meeting – 22-26 May 2016, Nantes, France, Society of Environmental Toxicology and Chemistry

[11] ARCHE (2013) Manufacture of metal compounds. spERC code Eurometaux 1.2.v2.1. Available online at http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/

STP	
Conditions and measures related to external treatment of waste for disposal	
Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the platinum content of the waste is elevated enough, internal or external recovery/recycling should be considered. **Fraction of daily/annual use** expected in waste: 0% **Appropriate waste codes:** 06 04 05*, 06 05 02*, 10 07 01, 10 07 02, 10 07 03, 10 07 05, 10 08 16, 15 02 02*, 16 01 18, 16 08 01, 16 08 06*, 16 08 07*, 19 08 06*, 20 01 40, **Suitable disposal:** Hazardous waste produced during the manufacture and downstream use is sent to a recycler only marginal amounts are sent to a landfill or an incinerator. Waste containing platinum is recycled for almost a 100% A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2016)	
Conditions and measures related to external recovery of waste	
Diammonium hexachloroplatinate- and other Pt -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility. The sludge from the on-site treatment plant is processed for metal reclamation (recycling).	
3. Exposure and risk estimation	

Environment [based on total Pt emissions]

ERC 1

ES 1 Production of Diammonium hexachloroplatinate*

Compartment	Unit	PNEC	$PEC_{regional}$	C_{local}	PEC	RCR	Methods for calculation of environmental concentrations

Discharge to STP (ES 1.1)	mg Pt/L	0.125 mg/L	N.A.	1.55×10^{-4} mg/L	1.55×10^{-4} mg/L	1.2×10^{-3}	Reasonable worst case exposure modelling based on 90P sector tonnage & 50P release factor
Freshwater via STP (ES 1.1)	mg Pt/L	1.4×10^{-4} mg/L	3.81×10^{-8} mg/L	4.71×10^{-6} mg/L	4.75×10^{-6} mg/L	3.39×10^{-2}	
Freshwater following direct discharge (ES 1.2)	mg Pt/L	1.4×10^{-4} mg/L	3.81×10^{-8} mg/L	3.51×10^{-7} mg/L	3.89×10^{-7} mg/L	2.78×10^{-3}	
Freshwater sediment via STP (ES 1.1)	mg Pt/kg w.w.	0.0568 mg/kg	N.A.[12]	1.92×10^{-3} mg/kg	1.92×10^{-3} mg/kg	0.34 ǂ	
Freshwater sediment via direct discharge (ES 1.2)	mg Pt/kg w.w.	0.0568 mg/kg	N.A.[12]	1.58×10^{-4} mg/kg	1.58×10^{-4} mg/kg	0.028 ǂ	
Terrestrial (ES 1.1 and 1.2)	mg Pt/kg w.w.	4.61×10^{-3} mg/kg	8.37×10^{-4} mg/kg	1.64×10^{-6} mg/kg	8.39×10^{-4} mg/kg	0.18	Modelled increase in soil concentrations due to deposition from atmospheric

[12] The concentration in freshly deposited sediment is taken as the PEC for sediment, therefore, the properties of suspended matter are used. The concentration in bulk sediment can be derived from the corresponding water body concentration, assuming a thermodynamic partitioning equilibrium. (ECHA (2016) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 3.0, February 2016))

							emissions (i.e. assuming no application of sewage sludge to land)

* All concentrations reported as Pt equivalent due to the Pt metal PNEC used for assessment.

ǂ Additional factor of 10 applied in RCR calculation to account for use of PNEC derived by equilibrium partitioning.

N.A. = not applicable

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Environment

Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool)

Scaling of the release to air and water environment includes:

- Refining of the release factor to air and waste water and/or and the efficiency of the air filter and wastewater treatment facility.
- Adjustment of the flow rate for the receiving water body and subsequent dilution factor.

9.1.2. Worker contributing scenario 1: Raw material handling (PROC 26, 21, 8b, 9, 1)

9.1.2.1. Conditions of use for handling of dry/dusty materials (PROC 26)

	Method
Product (article) characteristics	
• Physical form of substance: solid platinum substances	Monitoring data
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of dry/dusty platinum substances: - Generic local exhaust ventilation - Exterior exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Chloroplatinates are always handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.2.2. Exposure and risks for workers for handling of dry/dusty platinum substances (PROC 26)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 3. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	3.63 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.09 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:
  Number of measured data points: 17

The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #01 (GSD=3.7).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.2.3. Conditions of use for handling of non to low dusty platinum substances (PROC 21)

	Method
Product (article) characteristics	
• Physical form of substance: solid platinum substances	Monitoring data
• Maximum emission potential of the substance: Low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of chloroplatinates: - Generic local exhaust ventilation - Exterior exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - The physical form of the platinum substance may be considered as some containment considerably reducing emissions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.2.4. Exposure and risks for workers for handling of non to low dusty platinum substances (PROC 21)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 4. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.38 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.04 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:
  Number of measured data points: 3

The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.2.5. Conditions of use for handling of liquid platinum substances (PROC 8b, 9)

	Method
Product (article) characteristics	
• Physical form of substance: liquid (solution, suspension)	Monitoring data
• Maximum emission potential of the substance: Very low (It is noted that spraying operations are not covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of chloroplatinates in non to low dusty form: - Generic local exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Chloroplatinates are always handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.2.6. Exposure and risks for workers for handling of liquid platinum substances (PROC 8b, 9)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 5. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.38 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.04 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:
  Number of measured data points: 3

The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.2.7. Conditions of use for fully contained raw material handling (PROC 1)

	Method
Product (article) characteristics	
• Physical form of substance: not relevant (fully contained systems)	Monitoring data
• Maximum emission potential of the substance: not relevant (fully contained systems)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• Level of containment: - Full containment	
• Dermal exposure pattern: - Pattern of use: Closed system without breaches - Pattern of exposure control: Non-direct handling - Contact level: None	Analogous data
• Potential for contamination: Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.	

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.2.8. Exposure and risks for workers for fully contained raw material handling (PROC 1)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 6. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.01 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = not needed
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.004 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (all)

- Inhalation, systemic, long-term:
  Number of measured data points: 8

The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 12

  The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves)

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.3. Worker contributing scenario 2: Sampling/Evaluation (PROC 15)

9.1.3.1. Conditions of use for sampling/evaluation of solid platinum substances (PROC 15)

	Method
Product (article) characteristics	
• Physical form of substance: solid platinum substances	Monitoring data
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following type of exhaust ventilation is appropriate for handling of dry/dusty platinum substances: - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Platinum substances in solid form are always handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. Although automation may not be possible during evaluation/sampling, an incidental or intermittent contact level is achieved by limiting the number of exposure events (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.3.2. Exposure and risks for workers for sampling/evaluation of solid platinum substances (PROC 15)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 7. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	3.25 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.08 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

CES = contributing exposure scenario; ClPt = chloroplatinates; EC = Exposure concentration; EG = Exposure Group; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:

Number of measured data points: 14

The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #05 (GSD=4.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.3.3. Conditions of use for sampling/evaluation of liquid platinum substances (PROC 15)

	Method
Product (article) characteristics	
• Physical form of substance: liquid (solution, suspension)	Monitoring data Analogous data
• Maximum emission potential of the substance: Very low (It is noted that spraying operations are not covered in this assessment.)	Monitoring data Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data Analogous data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for sampling/evaluation of liquid platinum substances: - Generic local exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data Analogous data
• Level of containment: - The physical form of the platinum substance may be considered as some containment considerably reducing emissions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. Although automation may not be possible during evaluation/sampling, an incidental or intermittent contact level is achieved by limiting the number of exposure events (please refer to the dermal exposure pattern below).	
• Removal of residuals: Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.3.4. Exposure and risks for workers for sampling/evaluation of liquid platinum substances (PROC 15)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 8. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.15 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.02 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Analogous data (tracesClPt instead of ClPt data as exposure estimate was higher)

- Inhalation, systemic, long-term:
  Number of measured data points: 5

The estimated exposure level represents the maximum value multiplied with 1.5 of the exposure distribution for estimate #07 (GSD=5.8).

Monitoring data (ClPt)

- Inhalation, systemic, long-term:
  Number of measured data points: 2

  The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #06 (GSD=5.1).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.4. Worker contributing scenario 3: Wet processing (PROC 1, 2, 3, 4, 5)

9.1.4.1. Conditions of use for fully contained wet processing (PROC 1)

	Method
Product (article) characteristics	
• Physical form of substance: not relevant (fully contained systems)	Monitoring data
• Maximum emission potential of the substance: not relevant (fully contained systems)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for fully contained wet processing: - Generic local exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Full containment	
• Dermal exposure pattern: - Pattern of use: Closed system without breaches - Pattern of exposure control: Non-direct handling - Contact level: None	Analogous data
• Potential for contamination: Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.	

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.4.2. Exposure and risks for workers for fully contained wet processing (PROC 1)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.01 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = not needed
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.004 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (all)

- Inhalation, systemic, long-term:
  Number of measured data points: 8

The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 12

  The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves)

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.4.3. Conditions of use for not fully contained wet processes (PROC 2, 3, 4, 5)

	Method
Product (article) characteristics	
• Physical form of substance: liquid (solution, suspension)	Monitoring data
• Maximum emission potential of the substance: Very low (It is noted that spraying operations are not covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of chloroplatinates in non to low dusty form: - Generic local exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Chloroplatinates are always handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.4.4. Exposure and risks for workers for not fully contained wet processes (PROC 2, 3, 4, 5)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 10. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.68 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates;; EC = Exposure concentration; RC = Risk characterisation;

<u>Remarks on exposure data</u>

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:
  Number of measured data points: 21

The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #09 (GSD=2.5).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.5. Worker contributing scenario 4: Separation/Filtration (PROC 1, 2, 3, 4)

9.1.5.1. Conditions of use for fully contained separation/filtration (PROC 1)

	Method
Product (article) characteristics	
• Physical form of substance: not relevant (fully contained systems)	Monitoring data
• Maximum emission potential of the substance: not relevant (fully contained systems)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• The following type of exhaust ventilation is appropriate for fully contained separation/filtration: - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Full containment	
• Dermal exposure pattern: - Pattern of use: Closed system without breaches - Pattern of exposure control: Non-direct handling - Contact level: None	Analogous data
• Potential for contamination: Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.	

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.5.2. Exposure and risks for workers for fully contained separation/filtration (PROC 1)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 11. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.01 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = not needed
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.004 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Monitoring data (all)

- Inhalation, systemic, long-term:
  Number of measured data points: 8

The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 12

  The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves)

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.5.3. Conditions of use for handling of non to low dusty platinum substances (PROC 2, 3, 4)

	Method
Product (article) characteristics	
• Physical form of substance: solid platinum substances	Monitoring data
• Maximum emission potential of the substance: Low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of Pt substances in non to low dusty form: - Generic local exhaust ventilation - Exterior exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - The physical form of the platinum substance may be considered as some containment considerably reducing emissions. - Chloroplatinates are additionally handled in at least partly enclosed systems. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Extensive	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.5.4. Exposure and risks for workers for handling of non to low dusty platinum substances (PROC 2, 3, 4)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 12. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	4.08 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.10 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.29 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:
  Number of measured data points: 13

The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #013 (GSD=5.6).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 17

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDE in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.5.5. Conditions of use for handling of liquid platinum substances (PROC 2, 3, 4)

	Method
Product (article) characteristics	
• Physical form of substance: liquid (solution, suspension)	Monitoring data
• Maximum emission potential of the substance: Very low (It is noted that spraying operations are not covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of chloroplatinates in non to low dusty form: - Generic local exhaust ventilation - Exterior exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - The physical form of the platinum substance may be considered as some containment considerably reducing emissions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Removal of residuals: Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.5.6. Exposure and risks for workers for handling of liquid platinum substances (PROC 2, 3, 4)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 13. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.69 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:
  Number of measured data points: 5

The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #011 (GSD=8.1).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.6. Worker contributing scenario 5: Washing/Drying (PROC 1, 2, 3, 4)

9.1.6.1. Conditions of use for fully contained washing/drying (PROC 1)

	Method
Product (article) characteristics	
• Physical form of substance: not relevant (fully contained systems)	Monitoring data
• Maximum emission potential of the substance: not relevant (fully contained systems)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• The following type of exhaust ventilation is appropriate for fully contained washing/drying: - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Full containment	
• Dermal exposure pattern: - Pattern of use: Closed system without breaches - Pattern of exposure control: Non-direct handling - Contact level: None	Analogous data
• Potential for contamination: Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.	

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.6.2. Exposure and risks for workers for fully contained washing/drying (PROC 1)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 14. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.01 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = not needed
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.004 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Monitoring data (all)

- Inhalation, systemic, long-term:
  Number of measured data points: 8

The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 12

  The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves)

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.6.3. Conditions of use for handling of non to low dusty platinum substances (PROC 2, 3, 4)

	Method
Product (article) characteristics	
• Physical form of substance: solid platinum substances	Analogous data
• Maximum emission potential of the substance: Low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of chloroplatinates in non to low dusty form: - Generic local exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Analogous data
• Level of containment: - Chloroplatinates in non to low dusty form are always handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.6.4. Exposure and risks for workers for handling of non to low dusty platinum substances (PROC 2, 3, 4)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 15. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC required for EG, inhalation route	qualitative
EC inhalation, long-term, systemic	4.08 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.10 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC required for EG, dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Analogous data (ClPt separation/filtration)

- Inhalation, systemic, long-term:
  Number of measured data points: 13

The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #013 (GSD=5.6).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.6.5. Conditions of use for handling of liquid platinum substances (PROC 2, 3)

	Method
Product (article) characteristics	
• Physical form of substance: liquid (solution, suspension)	Analogous data
• Maximum emission potential of the substance: Very low (It is noted that spraying operations are not covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• The following type of exhaust ventilation is appropriate for handling of chloroplatinates in non to low dusty form: - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Analogous data
• Level of containment: Partly enclosed The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Removal of residuals: Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Incidental	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.6.6. Exposure and risks for workers for handling of liquid platinum substances (PROC 2, 3)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 16. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC required for EG, inhalation route	qualitative
EC inhalation, long-term, systemic	0.69 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC required for EG, dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Analogous data (ClPt separation/filtration)

- Inhalation, systemic, long-term:
  Number of measured data points: 5

The estimated exposure level represents the maximum value of the exposure distribution multiplied with 1.5 for estimate #011 (GSD=8.1).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.6.7. Conditions of use for processes at elevated temperature (PROC 2, 3)

	Method
Product (article) characteristics	
• Physical form of substance: dry/dusty solid	Analogous data
• Maximum emission potential of the substance: Medium (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• Process temperature: <150°C	Analogous data
• The following type of exhaust ventilation is appropriate for processes at elevated temperature: - Integrated exhaust ventilation A minimum efficiency of 90 % has to be assured.	Analogous data
• Level of containment: Partly enclosed	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.6.8. Exposure and risks for workers for processes at elevated temperature (PROC 2, 3)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 17. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	1.35 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 20: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Analogous data (ClPt calcination)

- Inhalation, systemic, long-term:
  Number of measured data points: 4

The estimated exposure level represents the maximum value of the exposure distribution for estimate #17 (GSD=2.6).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.7. Worker contributing scenario 6: Calcination (PROC 1)

9.1.7.1. Conditions of use for fully contained calcination (PROC 1)

	Method
Product (article) characteristics	
• Physical form of substance: not relevant (fully contained systems)	Monitoring data
• Maximum emission potential of the substance: not relevant (fully contained systems)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• Level of containment: - Full containment	
• Dermal exposure pattern: - Pattern of use: Closed system without breaches - Pattern of exposure control: Non-direct handling - Contact level: None	Analogous data
• Potential for contamination: Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.	

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.7.2. Exposure and risks for workers for fully contained calcination (PROC 1)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 18. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC required for EG, inhalation route	qualitative
EC inhalation, long-term, systemic	0.01 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = not needed
RC inhalation, long-term, systemic	risk adequately controlled
RC required for EG, dermal route	qualitative
EC dermal, long-term, systemic	0.004 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (all)

- Inhalation, systemic, long-term:
  Number of measured data points: 8

The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 12

  The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves)

<u>Conclusion on risk characterisation</u>

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.8. Worker contributing scenario 7: Milling/Grinding/Sieving (PROC 1)

9.1.8.1. Conditions of use for fully contained milling/grinding/sieving (PROC 1)

	Method
Product (article) characteristics	
• Physical form of substance: not relevant (fully contained systems)	Monitoring data
• Maximum emission potential of the substance: not relevant (fully contained systems)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• The following type of exhaust ventilation is appropriate for fully contained milling/grinding/sieving: - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Full containment	
• Dermal exposure pattern: - Pattern of use: Closed system without breaches - Pattern of exposure control: Non-direct handling - Contact level: None	Analogous data
• Potential for contamination: Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.	

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Due to the potential of cross-contamination, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.8.2. Exposure and risks for workers for fully contained milling/grinding/sieving (PROC 1)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 19. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC required for EG, inhalation route	qualitative
EC inhalation, long-term, systemic	0.01 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = not needed
RC inhalation, long-term, systemic	risk adequately controlled
RC required for EG, dermal route	qualitative
EC dermal, long-term, systemic	0.004 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (all)

- Inhalation, systemic, long-term:
  Number of measured data points: 8

The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 12

  The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves)

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.9. Worker contributing scenario 8: Packaging/Filling (PROC 21, 8b, 9, 1)

9.1.9.1. Conditions of use for handling of dry/dusty platinum substances (PROC 26)

	Method
Product (article) characteristics	
• Physical form of substance: solid platinum substances	Monitoring data
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of dry/dusty platinum substances: - Generic local exhaust ventilation - Exterior exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.9.2. Exposure and risks for workers for handling of dry/dusty platinum substances (PROC 26)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 20. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC required for EG, inhalation route	qualitative
EC inhalation, long-term, systemic	9.24 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.23 µg solPt/m³
RC inhalation, long-term, systemic	risk might not be adequately controlled
RC required for EG, dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk might not be adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:

Number of measured data points: 6

The estimated exposure level represents the maximum value of the exposure distribution for estimate #22 (GSD=7.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

The exposure arising from this contributing exposure scenario might exceed the benchmark value. As such it is not guaranteed that handling of dry/dusty platinum substances during packaging/filling can be done in a safe way in all the companies. Monitoring data up to P75 with RPE (APF = 40) do comply to the benchmark value. Companies exceeding the benchmark value should take additional risk management measures such as further enclosement of the process (see contributing exposure scenario: fully contained packaging/filling (PROC 1)).

9.1.9.3. Conditions of use for handling of non to low dusty platinum substances (PROC 21)

	Method
Product (article) characteristics	
• Physical form of substance: solid platinum substances	Monitoring data
• Maximum emission potential of the substance: Low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of chloroplatinates in non to low dusty form: - Generic local exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Chloroplatinates in solid form are always handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.9.4. Exposure and risks for workers for handling of non to low dusty platinum substances (PROC 21)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 21. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.38 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.04 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Analogous data (ClPt raw material handling)

- Inhalation, systemic, long-term:
  Number of measured data points: 3

The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.9.5. Conditions of use for handling of liquid platinum substances (PROC 8b, 9)

	Method
Product (article) characteristics	
• Physical form of substance: liquid (solution, suspension)	Monitoring data
• Maximum emission potential of the substance: Very low (It is noted that spraying operations are not covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of chloroplatinates in non to low dusty form: - Generic local exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Chloroplatinates are always handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.9.6. Exposure and risks for workers for handling of liquid platinum substances (PROC 8b, 9)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 22. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.38 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.04 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Analogous data (ClPt raw material handling)

- Inhalation, systemic, long-term:
  Number of measured data points: 3

The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of the use of appropriate gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.9.7. Conditions of use for fully contained packaging/filling (PROC 1)

	Method
Product (article) characteristics	
• Physical form of substance: not relevant (fully contained systems)	Monitoring data
• Maximum emission potential of the substance: not relevant (fully contained systems)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for fully contained wet processing: - Generic local exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Monitoring data
• Level of containment: - Full containment	
• Dermal exposure pattern: - Pattern of use: Closed system without breaches - Pattern of exposure control: Non-direct handling - Contact level: None	Analogous data
• Potential for contamination: Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.	

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.9.8. Exposure and risks for workers for fully contained packaging/filling (PROC 1)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 23. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.01 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = not needed
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.004 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (all)

- Inhalation, systemic, long-term:
  Number of measured data points: 8

  The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 12

  The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves)

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.10. Worker contributing scenario 9: Cleaning and maintenance (PROC 26, 8a)

9.1.10.1. Conditions of use for vacuum cleaning (PROC 26)

	Method
Product (article) characteristics	
• Physical form of substance: dusty residuals	Monitoring data
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• Removal of dusty residuals: A highly efficient vacuum cleaner is to be used. No direct manual removal of dust. Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry. Workplaces are to be cleaned before any maintenance work starts.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Extensive	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	

	Method
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.10.2. Exposure and risks for workers for vacuum cleaning (PROC 26)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 24. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	2.96 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.01 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:
  Number of measured data points: 17

The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNE in consideration of the use of appropriate gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.1.10.3. Conditions of use for wet cleaning (PROC 8a)

	Method
Product (article) characteristics	
• Physical form of substance: liquid (solution, suspension)	Monitoring data
• Maximum emission potential of the substance: Very low	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• Removal of residuals: Removal of residuals is considered to be part of regular work. Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry. Workplaces are to be cleaned before any maintenance work starts.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Extensive	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.10.4. Exposure and risks for workers for wet cleaning (PROC 8a)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 25. Exposure concentrations and risks for workers (for long-term, systemic effects, please see below for further qualitative assessments)

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	2.96 µg solPt/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.29 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

ClPt = chloroplatinates; EC = Exposure concentration; RC = Risk characterisation

<u>Remarks on exposure data</u>

Inhalation

Monitoring data (ClPt)

- Inhalation, systemic, long-term:
  Number of measured data points: 17

The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 17

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDE in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2. Exposure scenario 2: Use at industrial site - Use as an intermediate

Market sector: Manufacture of other substances

Sector of use:

SU 9, Manufacture of fine chemicals

SU 14, Manufacture of basic metals, including alloys

Environment contributing scenario(s):	
Use as an intermediate	ERC 6a
Worker contributing scenario(s):	
Handling of medium/high dusty materials	PROC 26
Handling of low dusty materials	PROC 26
Handling of solutions and reaction	PROC 3, 4, 5, 8b, 9, 15
Fully contained process	PROC 1
Reaction process	PROC 22
Wet powder production	PROC 27a
Hot powder production	PROC 27b
Wet cleaning	PROC 8a
Vacuum cleaning	PROC 26

Explanation on the approach taken for the ES

It is noted that this exposure scenario focusses on exposure to the substance to be registered. Please refer to information on safe use for the handling of the individual manufactured substances for process steps commencing the chemical transformation step.

9.2.1. Environmental contributing scenario 1: Use as an intermediate

9.2.1.1. Conditions of use

The conditions of use are as described in the generic exposure scenario (GES) below.

9.2.1.2. Releases

The GES and associated risk assessment are concerned with releases of Pt to wastewater and air arising from the use of diammonium hexachloroplatinate as an intermediate at an industrial site. Wastewater is treated by an on-site wastewater treatment plant (WWTP) prior to discharge to the receiving water body in a number of ways:

- To freshwater via a municipal sewage treatment plant (STP) [ES 2.1]; or
- Direct discharge to freshwater [ES 2.2].

Airborne emissions are treated by in-stack mitigation systems prior to discharge (all ES). Exposure assessment for the environment is based on representative exposure characteristics from the Pt manufacturing and processing sector for wastewater emissions and adjusted SpERC values for stack emissions to air (supported by a limited amount of emission data).

A sector-wide monitoring dataset is available, based on emissions of total Pt, resulting from production and use of a variety of Pt compounds collected during 2012 - 2016 from sites across Europe. In this assessment the release factor (RF) for wastewater is set at 0.00119 % (equivalent to 11.9 g/T); the 50th percentile measured wastewater release factor from 9 sites. The use of adjusted release factors for air is supported by the available data on measured Pt emissions in air at sites producing Pt compounds. In this assessment the release factor (RF) to air is set at 10% of the SpERC RF for 'manufacture of metal compounds'[13] to air of 0.03% (adjusted from 0.3% and equivalent to 30 g/T) is much higher than the mean measured RF of 15.7 g/T based on quantifiable measurements from four sites manufacturing Pt compounds.

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[13] http://www.arche-consulting.be/content/documents/Eurometaux-1.2.v2.1.pdf

9.2.1.3. Risk Management Measures (RMMs)

All sites from the Pt manufacturing and processing sector that provided data on emissions to water reported that wastewater treatment was primarily based on chemical precipitation followed by sedimentation and/or filtration. Two sites reported an additional step involving ion exchange. The reported efficiency for treatment of wastewater containing Pt compounds varied from 98 to 99.99%, with the majority of sites reporting $\geq$ 99.9% removal efficiency. Similarly, all sites reporting on RMMs for stack emissions to air (n=3) stated the use of wet scrubbers, with the reported efficiency in the range $\geq$ 99 %.

9.2.1.4. Exposure Scenario

The use of diammonium hexachloroplatinate as an industrial intermediate is considered to have the same operating conditions and emission characteristics as manufacture on the basis that many companies in this sector manufacture diammonium hexachloroplatinate for use as an intermediate and using facilities using this compounds as intermediate would be undertaking similar processes.

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for use of diammonium hexachloroplatinate as an intermediate at industrial sites is detailed below:

1. Title **ES2: Use as an intermediate at industrial site**	
Life cycle	Use as an intermediate at industrial site
Systematic title based on use descriptor	ERC: ERC 6A Use as an intermediate – industrial
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Use as an industrial intermediate

Systematic title based on use descriptor (environment)	ERC 6A Use as an intermediate – industrial
Processes, tasks, activities covered (environment)	Use as an industrial intermediate: delivery and processing of diammonium hexachloroplatinate, cleaning & maintenance.
Environmental Assessment Method	Estimates based on monitoring data of emissions, local and regional concentrations are used for calculation of PECs
Product characteristics Diammonium hexachloroplatinate as solid or aqueous solution. Environmental assessment is based on the estimated emission of diammonium hexachloroplatinate in wastewater discharge and in stack emissions to air.	
Amounts used	
Annual production/use at a site	ES 2.1 and ES 2.2: 68.3 tonnes diammonium hexachloroplatinate (30 tonnes Pt metal equivalent); 90P from sector data
Frequency and duration of use	
Pattern of release to the environment	330 days per year per site (50P from sector data)
Environment factors not influenced by risk management	
Receiving surface water flow rate	ES 2.1: STP: 3,000 m^3/d (minimum STP size from sector data) Receiving water: 93,000 m^3/d (based on 50P dilution factor from sector data) ES 2.2: Receiving water: 2,997,000 m^3/d (maximum allowable dilution factor of 1000; assumption made on

	knowledge of sector data.)
Dilution capacity, freshwater	ES 2.1: Discharge to freshwater via STP: DF in STP = 25; DF in receiving water = 32 (sector data) ES 2.2: Direct discharge to freshwater: DF = 1,000 (maximum allowable)
Dilution capacity, marine	Not relevent
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: All ES: On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99.9 % (sector data) Release factor after on-site treatment: 11.9 g/T (50P from sector data) ES 2.1. Off-site municipal sewage treatment plant (STP) Efficiency 57.1 % (based on European STP monitoring programme[14]) **Air:**	

[14] Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment. In: Abstracts Book of the SETAC Europe 26th Annual Meeting – 22-26 May 2016, Nantes, France, Society of Environmental Toxicology and Chemistry

All ES: Treatment of air emissions by wet scrubbers and filters (e.g. fabric, bag, HEPA). Release factor after on-site treatment: 30 g/T (10% of SpERC RF for 'Manufacture of metal compounds'[15])	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	
Municipal Sewage Treatment Plant (STP)	ES 2.1: Yes ES 2.2: No
Discharge rate of the Municipal STP	ES 2.1: 3 000 m^3/d (minimum from sector data)
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)
Conditions and measures related to external treatment of waste for disposal	
Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the platinum content of the waste is elevated enough, internal or external recovery/recycling should be considered. **Fraction of daily/annual use** expected in waste: 0% **Appropriate waste codes:** 06 04 05*, 06 05 02*, 10 07 01, 10 07 02, 10 07 03, 10 07 05, 10 08 16, 15 02 02*, 16 01 18, 16 08 01, 16 08 06*, 16 08 07*, 19 08 06*, 20 01 40, **Suitable disposal:** Hazardous waste produced during the manufacture and downstream use is sent to a recycler only marginal amounts are sent to a landfill or an incinerator. Waste containing platinum is recycled for almost a 100% A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2016)	

[15] ARCHE (2013) Manufacture of metal compounds. spERC code Eurometaux 1.2.v2.1. Available online at http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/

Conditions and measures related to external recovery of waste
Diammonium hexachloroplatinate- and other Pt -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility. The sludge from the on-site treatment plant is processed for metal reclamation (recycling).
3. Exposure and risk estimation

Environment [based on total Pt emissions]

ERC 6A

ES 2 Use as an industrial intermediate*

Compartment	Unit	PNEC	$PEC_{regional}$	C_{local}	PEC	RCR	Methods for calculation of environmental concentrations
Discharge to STP (ES 2.1)	mg Pt/L	0.125 mg/L	N.A.	1.55×10^{-4} mg/L	1.55×10^{-4} mg/L	1.2×10^{-3}	Reasonable worst case exposure modelling based on 90P sector tonnage & 50P release factor
Freshwater via STP (ES 2.1)	mg Pt/L	1.4×10^{-4} mg/L	3.81×10^{-8} mg/L	4.71×10^{-6} mg/L	4.75×10^{-6} mg/L	3.39×10^{-2}	
Freshwater following direct discharge (ES 2.2)	mg Pt/L	1.4×10^{-4} mg/L	3.81×10^{-8} mg/L	3.51×10^{-7} mg/L	3.89×10^{-7} mg/L	2.78×10^{-3}	

Freshwater sediment via STP (ES 2.1)	mg Pt/kg w.w.	0.0568 mg/kg	N.A.[16]	1.92 x 10^{-3} mg/kg	1.92 x 10^{-3} mg/kg	0.34 ‡	
Freshwater sediment via direct discharge (ES 2.2)	mg Pt/kg w.w.	0.0568 mg/kg	N.A.[16]	1.58 x10^{-4} mg/kg	1.58 x 10^{-4} mg/kg	0.028 ‡	
Terrestrial (ES 2.1 and 2.2)	mg Pt/kg w.w.	4.61 x 10^{-3} mg/kg	8.37 x10^{-4} mg/kg	1.64 x10^{-6} mg/kg	8.39 x 10^{-4} mg/kg	0.18	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)
* All concentrations reported as Pt equivalent due to the Pt metal PNEC used for assessment. ‡ Additional factor of 10 applied in RCR calculation to account for use of PNEC derived by equilibrium partitioning. N.A. = not applicable							
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES							

[16] The concentration in freshly deposited sediment is taken as the PEC for sediment, therefore, the properties of suspended matter are used. The concentration in bulk sediment can be derived from the corresponding water body concentration, assuming a thermodynamic partitioning equilibrium. (ECHA (2016) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 3.0, February 2016).

Environment Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool) Scaling of the release to air and water environment includes: • Refining of the release factor to air and waste water and/or and the efficiency of the air filter and wastewater treatment facility. • Adjustment of the flow rate for the receiving water body and subsequent dilution factor.

9.2.2. Worker contributing scenario 1: Handling of medium/high dusty materials (PROC 26)

9.2.2.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: solid	Analogous data
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate: - Generic local exhaust ventilation - Exterior exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Analogous data
• Level of containment: - Chloroplatinates have to be handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 26. Exposure concentrations and risks for workers

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	3.63 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.09 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

Remarks on exposure data

Inhalation

Analogous data (ClPt manufacturers raw material handling)

- Inhalation, systemic, long-term:
  Number of measured data points: 17

  The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #01 (GSD=3.7).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.3. Worker contributing scenario 2: Handling of low dusty materials (PROC 26)

9.2.3.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: solid	Analogous data
• Maximum emission potential of the substance: Low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate: - Generic local exhaust ventilation - Exterior exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Analogous data
• Level of containment: - The physical form of the platinum substance may be considered as some containment considerably reducing emissions. - Chloroplatinates have to be handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 27. Exposure concentrations and risks for workers

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.38 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.04 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

Remarks on exposure data

Inhalation

Analogous data (ClPt manufacturers raw material handling)

- Inhalation, systemic, long-term:
  Number of measured data points: 3

  The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

9.2.4. Worker contributing scenario 3: Handling of solutions and reaction (PROC 3, 4, 5, 8b, 9, 15)

9.2.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: liquid (solution, suspension)	Analogous data
• Maximum emission potential of the substance: Very low (It is noted that spraying operations are not covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate: - Generic local exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Analogous data
• Level of containment: - Chloroplatinates have to be handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 28. Exposure concentrations and risks for workers

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.68 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

Remarks on exposure data

Inhalation

Analogous data (ClPt manufacturers wet processing)

- Inhalation, systemic, long-term:
  Number of measured data points: 21

  The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #09 (GSD=2.5).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.5. Worker contributing scenario 4: Fully contained process (PROC 1)

9.2.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: not relevant (fully contained systems)	Analogous data
• Maximum emission potential of the substance: not relevant (fully contained systems)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Technical and organisational conditions and measures	
• Level of containment: - Full containment	
• Dermal exposure pattern: - Pattern of use: Closed system without breaches - Pattern of exposure control: Non-direct handling - Contact level: None	Analogous data
• Potential for contamination: Although the process as such is fully contained, exposure from adjacent workplaces may lead to contamination. Please consider the need for personal protective equipment in these cases.	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves as precautionary measure: Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 29. Exposure concentrations and risks for workers

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	0.01 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	not required
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.004 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

Remarks on exposure data

Inhalation

Analogous data (ClPt manufacturers separation/filtration)

- Inhalation, systemic, long-term:
  Number of measured data points: 8

  The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 12

  The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves)

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.6. Worker contributing scenario 5: Reaction process (furnace operation) (PROC 22)

9.2.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: not relevant	Analogous data
• Maximum emission potential of the substance: Low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Technical and organisational conditions and measures	
• Process temperature: below melting point	Analogous data
• The following type of exhaust ventilation is appropriate for processes at elevated temperature: - Integrated exhaust ventilation A minimum efficiency of 90 % has to be assured.	Analogous data
• Level of containment: - Chloroplatinates have to be handled in at least partly enclosed systems. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 30. Exposure concentrations and risks for workers

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	1.35 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 20: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

Remarks on exposure data

Inhalation

Analogous data (ClPt manufacturers calcination)

- Inhalation, systemic, long-term:
  Number of measured data points: 4

  The estimated exposure level represents the maximum value of the exposure distribution for estimate #17 (GSD=2.6).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

<u>Conclusion on risk characterisation</u>

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.7. Worker contributing scenario 6: Hot powder production (PROC 27a)

9.2.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: molten / powder (already other substance)	Analogous data
• Maximum emission potential of the substance: Medium (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Technical and organisational conditions and measures	
• Process temperature: Slightly above melting point	Analogous data
• The following type of exhaust ventilation is appropriate for processes at elevated temperature: - Integrated exhaust ventilation A minimum efficiency of 90 % has to be assured.	Analogous data
• Level of containment: - Chloroplatinates have to be handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 31. Exposure concentrations and risks for workers

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	1.35 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 20: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

Remarks on exposure data

Inhalation

Analogous data (ClPt manufacturer calcination)

- Inhalation, systemic, long-term:
  Number of measured data points: 4

  The estimated exposure level represents the maximum value of the exposure distribution for estimate #17 (GSD=2.6).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.8. Worker contributing scenario 7: Wet powder production (PROC 27b)

9.2.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Wetted, solutions, suspensions	Analogous data
• Maximum emission potential of the substance: Low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• The following type of exhaust ventilation is appropriate: - Integrated exhaust ventilation A minimum efficiency of 80 % has to be assured.	Analogous data
• Level of containment: - Chloroplatinates have to be handled in at least partly enclosed systems. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.8.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 32. Exposure concentrations and risks for workers

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	1.04 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 20: 0.05 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	<1 µg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

Remarks on exposure data

Inhalation

Analogous data (ClPt manufacturers separation/filtration)

- Inhalation, systemic, long-term:
  Number of measured data points: 3

  The estimated exposure level represents the maximum value of the exposure distribution for estimate #012 (GSD=3.4).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNI in consideration of the use of appropriate gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.9. Worker contributing scenario 8: Wet cleaning (PROC 8a)

9.2.9.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: liquid (solution, suspension)	Analogous data
• Maximum emission potential of the substance: Very low	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Technical and organisational conditions and measures	
• Removal of residuals: Removal of residuals is considered to be part of regular work. Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry. Workplaces are to be cleaned before any maintenance work starts.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Extensive	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.9.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 33. Exposure concentrations and risks for workers

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	2.96 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.29 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

Remarks on exposure data

Inhalation

Analogous data (ClPt manufacturers cleaning and maintenance)

- Inhalation, systemic, long-term:
  Number of measured data points: 17

  The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 17

  The estimated exposure level represents the 90th percentile of the exposure distribution for NDE in consideration of appropriate use of gloves.

<u>Conclusion on risk characterisation</u>

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

9.2.10. Worker contributing scenario 9: Vacuum cleaning (PROC 26)

9.2.10.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: dusty residuals	Analogous data
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if platinum substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data

	Method
Technical and organisational conditions and measures	
• Removal of dusty residuals: A highly efficient vacuum cleaner is to be used. No direct manual removal of dust. Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry. Workplaces are to be cleaned before any maintenance work starts.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Extensive	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	

	Method
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.10.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 34. Exposure concentrations and risks for workers

	ClPt
RC inhalation route	qualitative
EC inhalation, long-term, systemic	2.96 µg solPt/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.07 µg solPt/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.01 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

Remarks on exposure data

Inhalation

Analogous data (ClPt manufacturers cleaning and maintenance)

- Inhalation, systemic, long-term:
  Number of measured data points: 17

  The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNE in consideration of the use of appropriate gloves.

Conclusion on risk characterisation

Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.2.3.

Under the prescribed conditions of use, exposure is maintained at a very low level and the risk for any adverse health effects is minimised to the technically feasible level. Therefore, risks are adequately controlled.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

This chapter describes why a separate risk characterisation related to combined exposure is not required. Combined exposure may result from any of the following scenarios:

1. Multiple platinum substances handled in parallel at the same workplace,
2. More than just a single contributing occupational exposure scenario relevant for an individual worker,
3. Workers that are also exposed to platinum substances in their free time are not considered relevant as soluble platinum substances are not available for consumers.

These scenarios are considered below:

1. Multiple platinum substances handled in parallel at the same workplace

Exposure monitoring data were obtained from a number of workplaces where platinum and/or platinum substances are manufactured or used in parallel. Any samples are analysed for their soluble platinum content rather than for the content of the respective platinum substance. Thus, measured soluble platinum levels are intrinsically reflective of any potential parallel exposure to multiple soluble platinum substances and are not only relevant for a single platinum substance. An exposure assessment based on such monitoring data can therefore be considered to include an assessment for any platinum substance handled in parallel.

2. More than just a single contributing occupational exposure scenario relevant for an individual worker

For aggregated exposure resulting from the applicability of more than just a single contributing worker scenario in a single work shift, it is noted that all exposure levels were derived for a full-shift exposure time and a safe use was demonstrated for each contributing scenario. Thus, by demonstrating safe use for individual contributing scenarios it is assured that a combination of activities within a single shift, could not lead to any adverse effect.

10.1.2. Consumer

Not relevant.

10.2. Environment (combined for all emission sources)

All exposure scenarios detailed in this document include estimates of background concentrations of total platinum in fresh and marine waters and sediments (calculated using the EUSES model and an assumption of 50 % of the continental tonnage being manufactured and used in one region). Measured regional background concentrations of platinum in soil are taken from the GEMAS database. The ES for manufacturing and industrial intermediate use is based on a sector-wide approach based on monitoring data for total platinum and considering ALL forms of platinum processed at these sites. Additionally, each member company of the PMRC processing platinum compounds has a site-specific risk assessment based on the manufacture and use of all platinum compounds at their site; each of these assessments demonstrates an acceptable level of risk. and they are available from each member company on request.

Annexes

1. Annex: References

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2. Annex: Information on Test Material

Test material: **Platinum (IV)**
Form:

Composition type: Constituent	**Reference substance:** Platinum (IV) EC no.: CAS no: IUPAC name: Platinum (IV)	**Concentration range:**

Details on test material: Plasma emission standard, in 1 M HCl Source: BDH

Test material: **Pt(IV)**
Form: **gas under pressure: refrigerated liquefied gas**

Composition type: Constituent	**Reference substance:** Pt(IV) EC no.: CAS no: IUPAC name: Pt(IV)	**Concentration range:**

Details on test material: 10000 ppm Pt(IV) plasma emission standard in 1.2 M HCl Source: BDH

Test material: **Platinum (IV)**
Form:

Composition type: Constituent	**Reference substance:** Platinum (IV) EC no.: CAS no: IUPAC name: Platinum (IV)	**Concentration range:**

Details on test material: H2PtCl3in 7 % HCl, 1000 ppm ICP-OES standards (CertiPur, Merck)

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form:

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): ammonium hexachloroplatinate - Substance type: yellow powder - Physical state: solid - Lot/batch No.: 57662

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Ammonium hexachloroplatinate - Substance type: yellow powder - Physical state: solid - Lot/batch No.: 57662

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Ammonium hexachloroplatinate(IV) -

Substance type: yellow powder - Physical state: solid - Analytical purity: “99.9% purity of the metal used for production of this compound” - Lot/batch No.: 231/08-91 - Stability under test conditions: “stable throughout the experimental period” - Storage condition of test material: Kept dry in a container in a refrigerator

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form:

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Ammonium hexachloroplatinate - Substance type: yellow powder - Physical state: solid - Lot/batch No.: no data

Test material: **Ammonium hexachloroplatinate IV**
Form: **dissolved in DMSO**

Composition type: Constituent	**Reference substance:** Ammonium hexachloroplatinate IV EC no.: CAS no: IUPAC name: Ammonium hexachloroplatinate IV	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Ammonium hexachloroplatinate IV - Molecular formula (if other than submission substance): Cl6-Pt.2H4-N - Molecular weight (if other than submission substance): 444 g/mol - Smiles notation (if other than submission substance): Pt+4]([Cl-])([Cl-])([Cl-])([Cl-])([Cl-])[Cl-].[NH4+].[NH4+] - InChl (if other than submission substance): InChI=1S/6ClH.2H3N.Pt/h6*1H;2*1H3;/q;;;;;;;;+4/p-4 - Structural formula attached as image file (if other than submission substance): see Fig. - Substance type: Technical product - Physical state: No data - Analytical purity: 99.99% - Impurities (identity and concentrations): No data - Purity test date: No data - Lot/batch No.: No data - Stability under test conditions: No data - Storage condition of test material: No data - Other: Source Aldrich Chemical Co., Gillingham, UK

Test material: **Disodium hexachloroplatinate hexahydrate; Na2[PtCl6].6H2O**
Form: **not specified**

Composition type: Constituent	**Reference substance:** Disodium hexachloroplatinate hexahydrate EC no.: CAS no: IUPAC name: Disodium hexachloroplatinate hexahydrate	**Concentration range:**
Composition type: Constituent	**Reference substance:** Na2[PtCl6].6H2O EC no.: CAS no: IUPAC name: Na2[PtCl6].6H2O	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Disodium hexachloroplatinate - Molecular formula (if other than submission substance): Na2[PtCl6].6H2O - Molecular weight (if other than submission substance): 561.9 g/mol - Smiles notation (if other than submission substance): [Pt+4]([Cl-])([Cl-])([Cl-])([Cl-])([Cl-])[Cl-].[Na+].[Na+] (dehydrated form) - InChl (if other than submission substance): 1S/6ClH.2Na.Pt/h6*1H;;;/q;;;;;;2*+1;+4/p-6 (dehydrated form) - Structural formula attached as image file (if other than submission substance): see Fig. (dehydrated form) - Substance type: Technical product - Physical state: No data - Analytical purity: No data - Lot/batch No.: No data - Stability under test conditions: No data - Storage condition of test material: No data - Other: supplied by Degussa AG (Hanau, Germany)

Test material: **Diammonium hexachloroplatinate**
Form:

Composition type:	**Reference substance:** diammonium	**Concentration range:**

Constituent	hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	

Test material: **Sodium hexachloroplatinate; disodium hexachloroplatinate(2-) / 16923-58-3 / 240-983-5; hexachloroplatinic acid / 16941-12-1 / 241-010-7**
Form:

Composition type: Constituent	**Reference substance:** hexachloroplatinic acid EC no.: CAS no: 16941-12-1 IUPAC name: hexachloroplatinic acid	**Concentration range:**
Composition type: Constituent	**Reference substance:** Sodium hexachloroplatinate EC no.: CAS no: IUPAC name: Sodium hexachloroplatinate	**Concentration range:**
Composition type: Constituent	**Reference substance:** disodium hexachloroplatinate EC no.: CAS no: 16923-58-3 IUPAC name: disodium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: Hexachloroplatinic acid CAS# 16941-12-1 Sodium hexachloroplatinate CAS# 16923-58-3

Test material: **hexachloroplatinic acid / 16941-12-1 / 241-010-7**
Form:

Composition type: Constituent	**Reference substance:** hexachloroplatinic acid EC no.: CAS no: 16941-12-1 IUPAC name: hexachloroplatinic acid	**Concentration range:**

Details on test material: CAS 16941-12-1

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **not specified**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Ammonium hexachloroplatinate (AHCP) - Substance type: no data. - Physical state: no data. - Analytical purity: no data. - Impurities (identity and concentrations): no data. - Composition of test material, percentage of components: no data. - Isomers composition: no data. - Purity test date: no data. - Lot/batch No.: no data. - Expiration date of the lot/batch: no data. - Stability under test conditions: no data. - Storage condition of test material: no data.

Test material: **Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** Potassium hexachloroplatinate EC no.: CAS no: IUPAC name: Potassium hexachloroplatinate	**Concentration range:**
Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: Presumably exposure was mostly to potassium hexachloroplatinate, but this was not explicitly stated; workers were said to be exposed to “platinum salts”. In the factory, dissolved “platinum” from catalysts is processed to make potassium hexachloroplatinate powder, which is further processed to make metallic platinum and platinum-containing catalysts.

Test material: **Chloroplatinates & Tetaammine platinum dichloride (TPC)**
Form: **Airborne [possibly particulate matter]**

Composition type: Constituent	**Reference substance:** Chloroplatinates & Tetaammine platinum dichloride (TPC) EC no.: CAS no: IUPAC name: Chloroplatinates & Tetaammine platinum dichloride (TPC)	**Concentration range:**

Test material: **Chloroplatinum salts (as soluble platinum)**
Form: **Airborne [possible total dust as opposed to inhalable fraction]**

Composition type: Constituent	**Reference substance:** Chloroplatinum salts (as soluble platinum) EC no.: CAS no: IUPAC name: Chloroplatinum salts (as soluble platinum)	**Concentration range:**

Details on test material: Soluble platinum

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): diammonium hexachloroplatinate. - Substance type: organometallic. - Physical state: solid. - Analytical purity: salt assumed 100% pure. - Impurities (identity and concentrations): total metallic impurities (excluding Na) < 0.1%; sodium 0.2%. - Composition of test material, percentage of components: 37.99% w/w platinum. - Isomers composition: not applicable. - Purity test date: 01 July 2013. - Lot/batch No.: UZ0129-1. - Expiration date of the lot/batch: 5 years from the date of manufacture [01 July 2018] if packaging is intact and material is stored under described conditions. - Stability under test conditions: as above. - Storage condition of test material: At +10degC to +25degC, in a tightly closed container, protected from direct sunlight.

Test material: **dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form: **In [presumably aqueous] solution**

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: Potassium hexachloroplatinate (CAS 16921-30-5) Purchased from Chemical Procurement Labs, Inc. Stored in the dark; CAS not provided.

Test material: **K2PtCl6; Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Potassium hexachloroplatinate EC no.: CAS no: IUPAC name: Potassium hexachloroplatinate	**Concentration range:**
Composition type: Constituent	**Reference substance:** K2PtCl6 EC no.: CAS no: IUPAC name: K2PtCl6	**Concentration range:**

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **not specified**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): (NH4)2PtCl6

Test material: **(NH4)2PtCl6; 1332-76-9 / 1332-76-9; Ammonium hexachloroplatinate (IV)**
Form:

Composition type: Constituent	**Reference substance:** Ammonium hexachloroplatinate (IV) EC no.: CAS no: IUPAC name: Ammonium hexachloroplatinate (IV)	**Concentration range:**
Composition type: Constituent	**Reference substance:** 1332-76-9 EC no.: CAS no: 1332-76-9 IUPAC name: 1332-76-9	**Concentration range:**
Composition type: Constituent	**Reference substance:** (NH4)2PtCl6 EC no.: CAS no: IUPAC name: (NH4)2PtCl6	**Concentration range:**

Details on test material: Note: the test material CAS and molecular formula as given in the publication (and cited above) are inconsistent. The molecular formula relates to the diammonium form and the CAS to the mono-ammonium form; the given name is used as a synonym for either.

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form:

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Not reported - Substance type: yellow powder - Physical state: solid - Analytical purity: no data - Purity test date: - Lot/batch No.: no data - Expiration date of the lot/batch: no data - Stability under test conditions: no data - Storage condition of test material: no data on storage condition; solutions prepared immediately before testing

Test material: **(NH4)2PtCl6; Ammonium hexachloroplatinate**
Form:

Composition type: Constituent	**Reference substance:** Ammonium hexachloroplatinate EC no.: CAS no: IUPAC name: Ammonium hexachloroplatinate	**Concentration range:**
Composition type: Constituent	**Reference substance:** (NH4)2PtCl6 EC no.: CAS no: IUPAC name: (NH4)2PtCl6	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): ammonium hexachloroplatinate (CAS not reported) - Analytical purity: “Of the highest purity commercially available” in Japan. - Source: purchased through Maruichi Chemical Ltd., Misima

Test material: **Potassium hexachloroplatinate; dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Potassium hexachloroplatinate EC no.: CAS no: IUPAC name: Potassium hexachloroplatinate	**Concentration range:**

Test material: **dipotassium hexachloroplatinate(2-) / 16921-30-5 / 240-979-3**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloroplatinate EC no.: CAS no: 16921-30-5 IUPAC name: dipotassium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): K2PtCl6(IV); CAS RN 16921-30-5

Test material: **(NH4)2PtCl6; Ammonium hexachloroplatinate**

Form:

Composition type: Constituent	**Reference substance:** Ammonium hexachloroplatinate EC no.: CAS no: IUPAC name: Ammonium hexachloroplatinate	**Concentration range:**
Composition type: Constituent	**Reference substance:** (NH4)2PtCl6 EC no.: CAS no: IUPAC name: (NH4)2PtCl6	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Ammonium hexachloroplatinate (CAS not reported) - Analytical purity: “Of the highest purity commercially available” in Japan. - Source: purchased through Maruichi Chemical Ltd., Misima

Test material: **diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**

Details on test material: - Physical description: Orange Powder - Batch Number: YS1 - Storage and Handling: stored at room temperature in the dark

Test material: **hexachloroplatinic acid / 16941-12-1 / 241-010-7**
Form:

Composition type: Constituent	**Reference substance:** hexachloroplatinic acid EC no.: CAS no: 16941-12-1 IUPAC name: hexachloroplatinic acid	**Concentration range:**

Test material: **85392-65-0 / 286-924-7; Tetraammonium decachloro-mu-oxodiruthenate (4-)**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** Tetraammonium decachloro-mu-oxodiruthenate(4-) EC no.: CAS no: 85392-65-0 IUPAC name: Tetraammonium decachloro-mu-oxodiruthenate(4-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Tetraammonium decachloro-mu-oxodiruthenate (4-) EC no.: CAS no: IUPAC name: Tetraammonium decachloro-mu-oxodiruthenate (4-)	**Concentration range:**

Details on test material: - Physical description: Black powder - Batch Number: RHV315 - Storage and Handling: stored at room temperature in the dark

Test material: **16941-12-1 / 241-010-7**
Form: **liquid**

Composition type:	**Reference substance:**	**Concentration range:**

Constituent	Hexachloroplatinic acid EC no.: CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	

Details on test material: - Colour/form: orange liquid - Density: 2.069 g/mL

Test material: **Platinate(2-), hexachloro-, diammonium; diammonium hexachloroplatinate(2-) / 16919-58-7 / 240-973-0**
Form: **solid**

Composition type: Constituent	**Reference substance:** diammonium hexachloroplatinate EC no.: CAS no: 16919-58-7 IUPAC name: diammonium hexachloroplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Platinate(2-), hexachloro-, diammonium EC no.: CAS no: IUPAC name: Platinate(2-), hexachloro-, diammonium	**Concentration range:**

Details on test material: - Physical state: Yellow crystalline powder - Stability under test conditions: Stable under normal conditions - Storage condition of test material: Protected from direct sunlight in a dry and well-ventilated area at 15-30 °C

Test material: **16941-12-1 / 241-010-7**
Form: **solid**

Composition type: Constituent	**Reference substance:** Hexachloroplatinic acid EC no.: CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	**Concentration range:**

Test material: **Hexachloroplatinic acid**
Form:

Composition type: Constituent	**Reference substance:** hexachloroplatinic acid EC no.: CAS no: 16941-12-1 IUPAC name: hexachloroplatinic acid	**Concentration range:**

Test material: **Platinum(IV) chloride**
Form:

Composition type: Constituent	**Reference substance:** Platinum(IV) chloride EC no.: CAS no: 13454-96-1 IUPAC name: Tetrachloroplatinum	**Concentration range:**

Test material: **Hexachloroplatinic acid**
Form: **Resin**

Composition type: Constituent	**Reference substance:** Hexachloroplatinic acid EC no.:	**Concentration range:**

	CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	

3. Annex: Mode of action / Human relevance Framework

Section 5.6.3: Repeated dose toxicity.001
Detailed information on mode of action / Human relevance framework:

No data identified.

Section 5.7.3: Genetic toxicity
Detailed information on mode of action / Human relevance framework:

No data identified.

Section 5.9.3: Toxicity to reproduction.001
Detailed information on mode of action / Human relevance framework:

No data identified.