CHEMICAL SAFETY REPORT

Substance Name: dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2)
EC Number: 268-717-3
CAS Number: 68133-90-4
Registrant's Identity: Predefined Legal entity

Table of Contents

List of Tables

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

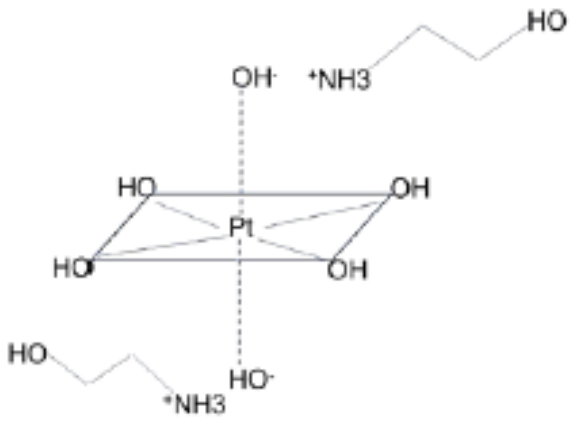
1.1. Name and other identifiers of the substance

The substance dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) is a mono-constituent substance (organometallic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).
The following public name is used:

Table 1.1. Substance identity

EC number:	268-717-3
EC name:	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2)
CAS number (EC inventory):	68133-90-4
CAS number:	68133-90-4
IUPAC name:	dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)
Synonyms:	Platinate (Pt(OH)62-), (OC-6-11)-, dihydrogen, compd. with 2-aminoethanol (1:2)
Molecular formula:	C2H7NO.1/2H6O6Pt.H
Molecular weight range:	419.295

Structural formula:



1.2. Composition of the substance

Overall information on composition:

Composition	Related composition(s)	Related assessment entity
Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) (legal entity composition of the substance)		dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol
Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol		dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol Pt dissolved

(1:2) - Registration boundary conditions (boundary composition of the substance)		

Name: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2)

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

Table 1.2. Constituents (Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2))

Constituent	Typical concentration	Concentration range	Remarks
dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3	% (w/w)	% (w/w)	

Table 1.3. Impurities (Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2))

Constituent	Typical concentration	Concentration range	Remarks
2-aminoethanol EC no.: 205-483-3	% (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, Na) 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: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) - Registration boundary conditions

(boundary composition of the substance)
State/form: Solution
Degree of purity: >=95 - <=99 % (w/w)
Description: Mono-constituent substance The composition provided is the theoretical composition of a pure solution of Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2). In practice, Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) is brought on the market in an aqueous solution containing 20-50 % Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2). 2-aminoethanol is intentionally added to preserve the substance's stability (it keeps the pH high to prevent the decomposition of the substance).

Table 1.4. Constituents (Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) - Registration boundary conditions)

Constituent	Typical concentration	Concentration range	Remarks
dihydrogen hexahydroxyplatinate, compound with 2-	97 % (w/w)	>=95 - <=99 % (w/w)	

aminoethanol (1:2) EC no.: 268-717-3			

Table 1.5. Impurities (Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) - Registration boundary conditions)

Constituent	Typical concentration	Concentration range	Remarks
2-aminoethanol EC no.: 205-483-3	3 % (w/w)	>=1 - <5 % (w/w)	
Impurities EC no.:	<0.1 % (w/w)	>=0 - <=0.5 % (w/w)	Several minor (especially metallic, e.g. Ag, Au, Cu, Ir, Pb, Pd, Rh, Ru, Na) 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

1.3. Assessment entity information

Assessment entity name	Remarks
dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Assessment entity composition: The composition(s) for this assessment entity is the one listed in section 1.2 (Composition of the Substance)
Pt dissolved	Assessment entity composition: platinum EC no.: 231-116-1 Additional information: **For this category of platinum(IV) substances, it is proposed that, in environmental media, the substances (partly) dissolve. Only the dissolved species are capable of exerting effects on organisms. The counterions dissociate from the platinum moiety / platinum complex with the formation of [Pt(OH)2]0as the dominant Pt species upon equilibrium and a free Pt-ion concentration that is vanishingly low (<<10-10M). It should be noted that this represents a chemical transformation and not a "biotransformation". The counterions do not contribute significantly to the observed effect(s), and these effects (expressed as dissolved platinum concentration) are similar for the different category members.** **More details are provided in the Read Across Justification Document, attached in IUCLID Section 13.**

1.4. Physicochemical properties

Table 1.6. Physicochemical properties

Property	Value used for CSA / Discussion	Description of key information	Assessment

			entity linked
Physical state	**liquid at 20°C and 101.3 kPa** The information on appearance and physical state of the substance is taken from the test material section of a GLP-compliant ecotoxicity study (Simon 2016) and is therefore considered to be suitable for use for this endpoint. Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol is a yellow-orange liquid.	Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol is a yellow-orange liquid.	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol Pt dissolved
Melting / freezing point	**-8°C at 101.3 kPa** Nau (2017) is a GLP-compliant study following OECD guideline 102 and EU method A1. It is reliable without restrictions and can be used as a key study for this endpoint. Melting point was determined using differential scanning calorimetry. The test item had a mean melting point of -8.0°C.	The test item had a mean melting point of -8.0°C.	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol Pt dissolved
Boiling point	**100.5°C at 101.3 kPa** Nau (2017) is a GLP-compliant study following OECD guideline 103 and EU method A2. It is reliable without restrictions and can be used as the key study for this endpoint. Boiling point was determined using differential scanning calorimetry and corrected to atmospheric pressure. The test item had a mean boiling point of 100.5°C at 1013.3 hPa. Boiling was incomplete (mass loss 80%).	The test item had a mean boiling point of 100.5°C at 1013.3 hPa. Boiling was incomplete (mass loss 80%).	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol Pt dissolved
Relative density	**1.23 at 20°C** Nau (2018) is a GLP-compliant study following OECD guideline 109 and EU method A3. It is reliable without restrictions and can be used as the key study for this endpoint. Density was determined using an oscillating densitometer. The relative density of the test item at 20°C (compared to water at 4°C) is 1.23.	The relative density of the test item at 20°C (compared to water at 4°C) is 1.23.	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol

Vapour pressure	**23.9hPa at 20°C** Mekelburger (2002) follows OECD guideline 104 without deviation and is conducted to GLP. The study is considered reliable and can be used as the key study for this endpoint. The vapour pressure of a bis(ethanolammonium)hexahydroxoplatinate solution containing approximately 10% platinum is 23.9 hPa at 20°C.	The vapour pressure of a bis(ethanolammonium)hexahydroxoplatinate solution containing approximately 10% platinum is 23.9 hPa at 20°C.	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol Pt dissolved
Partition coefficient n-octanol/water (log value)	**Log Kow (Log Pow): -1.31 at 20°C** Partition coefficient is not relevant for inorganic substances, therefore only the log Kow for the organic component of this substance is reported. This information is taken from a reliable peer reviewed handbook (Hansch et al 1995) and so can be considered suitable for use as the key study for this endpoint. The log kow of ethanolamine is -1.31.	Partition coefficient is not relevant for inorganic substances, therefore only the log Kow for the organic component of this substance is reported. The log kow of ethanolamine is -1.31.	
Water solubility	Nau (2018) is a GLP-compliant study following OECD guideline 105 and EU method A6. It is reliable without restrictions and can be used as the key study for this endpoint. The flask method was used, based on results from a preliminary test, but water solubility could not be determined. At the beginning of all experiments, the solution appeared homogeneous and slightly yellow without precipitate. After equilibration time, little precipitate was observed in the flasks of the 24 h experiment and no precipitate in the blank experiment. In the flasks of the 48 h and the 72 h experiments, a black precipitate was found. The test item is not stable in water at the concentration used. Adding water most likely leads to an equilibrium displacement generating a less soluble platinum species. For this reason, the water solubility was not determinable.	The test item is not stable in water at the concentration used. Adding water most likely leads to an equilibrium displacement generating a less soluble platinum species. For this reason, the water solubility was not determinable.	
	1g/L at 20°C		Pt dissolved

	A generic value has been included for dissolved Pt to assume full solubility once in the environment.		
Flash point	Nau (2017) is a GLP-compliant study following EU method A9. It is reliable without restrictions and can be used as the key study for this endpoint. No ignition was detected up to the beginning of boiling. The test was stopped at 106°C.	No ignition was detected up to the beginning of boiling. The test was stopped at 106°C.	

Data waiving

Information requirement: Granulometry

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is marketed or used in a non solid or granular form [study scientifically not necessary / other information available]

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: Self-ignition temperature

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is a liquid non flammable in air, e.g. no flash point up to 200°C [study scientifically not necessary / other information available] - In the flash point study, no ignition was detected up to the beginning of boiling. The test was stopped at 106°C. Due to the ongoing boiling the composition of the test item changes. These changes will become more and more pronounced with increasing temperatures. Additionally, if the temperature of the oven is above the boiling point a major part of the test item will vaporize after being put into the apparatus and hence fill the space above the remaining test item with vapour (in exchange of air: no flammable vapour/air mixture present). Therefore, a measurement of the flash point above the boiling point is not advisable.

Information requirement: Flammability

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is a liquid [study technically not feasible] - Flammability of liquids is determined based on flash point and boiling point.

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]

Information requirement: Oxidising 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 oxidising properties and hence, the classification procedure does not need to be applied [study scientifically not necessary / other information available]

Discussion of physicochemical properties

Additional information:

Physico-chemical endpoints are completed for this substance based on reliable test data for the substance itself and suitable data waivers.

Based on the test results and structure of the substance, dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol is not classified for physico-chemical endpoints.

2. MANUFACTURE AND USES

2.1. Manufacture

Table 2.1. Manufacture

	Manufacture
M-1	**Manufacture of the substance (as such)** Further description of manufacturing process: The insoluble substance Dihydrogen hexahydroxyplatinate is dissolved in a mixture of water and 2-aminoethanol. During the solution step the substance Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) is formed. The solution may be used for further processing and production of platinum compounds. Contributing activity/technique for the environment : **- Manufacture of the substance (as such) ES 1.1 (ERC1)** **- Manufacture of the substance (as such) ES 1.2 (ERC1)** Contributing activity/technique for the workers : **- Raw material handling of dry/dusty materials (PROC 26)** **- Raw material handling of non to low dusty platinum substances (PROC 21)** **- Raw material handling of liquid platinum substances (PROC 8b ; PROC 9)** **- Raw material handling of platinum substances in fully contained systems (PROC 1)** **- Sampling/Evaluation of solid platinum substances (PROC 15)** **- Sampling/Evaluation of liquid platinum substances (PROC 15)** **- Wet processing in fully contained systems (PROC 1)** **- Wet processing in not fully contained systems (PROC 2 ; PROC 3 ; PROC 4 ; PROC 5)** **- Packaging/Filling of liquid platinum substances (PROC 8b ; PROC 9)** **- Packaging/Filling in fully contained systems (PROC 1)** **- Cleaning and maintenance: vacuum cleaning (PROC 26)** **- Cleaning and maintenance: wet cleaning (PROC 8a)** use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Related assessment: use assessed in a joint CSR

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 : **- Use as an intermediate ES 2.1 (ERC6a)** **- Use as an intermediate ES 2.2 (ERC6a)** Contributing activity/technique for the workers : **- Handling of solutions or low dusty material and reaction (PROC 3 ; PROC 4 ; PROC 5 ; PROC 8b ; PROC 9 ; PROC 15 ; PROC 26)** **- Fully contained process (PROC 1)** **- 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) use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Substance supplied to that use: as such ; in a mixture Subsequent service life relevant for that use: no Related assessment: use assessed in a joint CSR

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Substance: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol
Implementation: EU
Related composition: Boundary Composition
The substance is classified as follows:

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 conclusive but not sufficient for classification
Flammable gases and chemically unstable gases:			data conclusive but not sufficient for classification
Flammable aerosols:			data conclusive but not sufficient for classification
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:			data conclusive but not sufficient for classification

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:			data conclusive but not sufficient for classification
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:	Skin Corr. 1B	H314: Causes severe skin burns and eye damage.	
Serious damage / eye irritation:	Eye Damage 1	H318: Causes serious eye damage.	
Respiratory sensitisation:			data lacking
Skin sensitisation:			data conclusive but not sufficient for classification
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:			data conclusive but not sufficient for classification

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):	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 lacking

Labelling

Signal word: Danger

Hazard pictogram:

GHS05: corrosion

Hazard statements:

H314: Causes severe skin burns and eye damage.

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.

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

P264: Wash ... thoroughly after handling.

P273: Avoid release to the environment.

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

P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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).

P363: Wash contaminated clothing before reuse.

P391: Collect spillage.

P405: Store locked up.

P501: Dispose of contents/container to ...

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

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 Pt 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).

Biodegradation has not been assessed for the substance as a whole as this endpoint is not relevant for inorganics. However, biodegradation potential of the organic component of the substance has been assessed (Kuenemann et al, 1992). Results are reported in a published paper, and although there are some limitations with the reporting of method details the paper is considered to be suitable for use for assessing this endpoint. Monoethanolamine (2-aminoethanol) was found to be readily biodegradable as the pass criterion of >70% degradation was met with 97 and 92% degradation observed.

A hydrolysis study has not been conducted for this substance as it is not considered to be scientifically necessary.

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 ‘remarks’ - In accordance with section 1 of REACH Annex XI, the hydrolysis study does not need to be conducted as this substance is not expected to undergo hydrolysis in the environment due to a lack of hydrolysable functional groups and therefore testing does not appear scientifically necessary.

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

The studies on biodegradation in water (screening tests) are summarised in the following table:

Table 4.1. Screening tests for biodegradation in water

Method	Results	Remarks
biodegradation in water: ready biodegradability: activated sludge, domestic, non-adapted (aerobic) according to tested with two ready biodegradability tests: Modified OECD Test and Modified Sturm Test	readily biodegradable % Degradation of test substance: 97 (% degradation (DOC removal)) (fresh sludge) 92 (Th02) (Modified sturm test)	2 (reliable with restrictions) key study experimental study **Test material** 2-aminoethanol, (full information in **Annex II**). **Reference** **Kuenemann, P., De Morsier, A. And Vasseur, P. 1992**

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

Discussion (screening testing)

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

Biodegradation is not relevant for inorganic substances, but as this substance has an organic component the biodegradation potential of the organic part of the test item has been assessed. Monoethanolamine (2-aminoethanol) was found to be readily biodegradable.

Value used for CSA:
Biodegradation in water: readily biodegradable

Additional information:

Biodegradation is not relevant for inorganic substances, but as this substance has an organic component the biodegradation potential of the organic part of the test item has been assessed.

The substance was tested following two ready biodegradation methods, a modified OECD test and a modified sturm test (Kuenemann et al, 1992). Results are reported in a published paper, and although there are some limitations with the reporting of method details the paper is considered to be suitable for use for assessing this endpoint. Monoethanolamine (2-aminoethanol) was found to be readily biodegradable as the pass criterion of >70% degradation was met with 97 and 92% degradation observed.

4.1.2.2. Biodegradation in soil

No relevant information available.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

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

Table 4.2. 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: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol 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.)	2 (reliable with restrictions) supporting study experimental study

	Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	**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: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol 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 based on grouping of substances (category approach) **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: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol 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:

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.

For the exposure assessment the log Kd value from the suspended solids was used in case no value was available.

Value used for CSA:
Koc at 20°C:
Other adsorption coefficients:

- log Kp (solids-water in suspended matter) : 3.27
- log Kp (solids-water in soil) : 1.57
- log Kp (solids-water in sediment) : 3.27
- log Kp (solids-water in raw sewage sludge) : 3.27
- log Kp (solids-water in settled sewage sludge) : 3.27
- log Kp (solids-water in activated sewage sludge) : 3.27
- log Kp (solids-water in effluent sewage sludge) : 3.27

Assessment entity linked:
Pt dissolved. View the assessment entity table in chapter 1.3 **here**

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.

4.3. 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, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant (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:

HHPA:2AE is a complex of dihydrogen hexahydroxyplatinate (hexahydroxyplatinic acid, HHPA) and 2-aminoethanol (2-AE), in a 1:2 ratio. It is likely to be poorly absorbed after oral exposure, with rapid excretion of any material that is absorbed. Based primarily on experimental rat data on a water-soluble platinum salt, an oral absorption figure of 0.5% is proposed for chemical safety assessment (CSA) and DNEL calculation.

Although exposure by the inhalation route is anticipated to be low, inhalation absorption is potentially extensive. In line with ECHA guidance, a conservative default assumption of 100% inhalation absorption will be used for CSA and DNEL calculation (when extrapolating from an oral laboratory animal study to a human inhalation exposure).

Significant bioavailability after dermal exposure is also unlikely, notably based on experimental dermal penetration data (human in vitro studies), both for other Pt salts and for 2-AE. Noting the potential for disruption of the skin barrier caused by the corrosivity of HHPA:2AE, a value of 20% dermal absorption is proposed for CSA and DNEL calculation (when extrapolating from an oral laboratory animal study to a human dermal exposure).

No information is available on whether or not the HHPA:2AE complex breaks down in any way after administration (e.g. whether there is dissociation prior to Pt absorption). The physico-chemical properties of HHPA:2AE suggest that it has a potential for bioaccumulation in the adipose tissues. The potential for bioaccumulation of certain other metals and ions is also 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 – HHPA:2AE

No specific data on the oral absorption of the HHPA:2AE complex is available. Very limited insight can be gained from the observation that some signs of toxicity were observed in the combined repeated-

dose/reproductive and developmental toxicity study (OECD TG 422) on this complex (Hansen, 2017). CD rats (10/sex/group) were administered 0, 100, 300 or 1000 mg/kg bw/day by oral gavage for 36 treatment days (in males) or 50-63 treatment days (in females). High-dose animals displayed “slight to pronounced salivation” and slightly reduced motility; decreased food consumption and slightly reduced body weights (statistically significant only in males) and reduced body weight gain in comparison to controls were also reported in the high-dose animals. This may suggest that some systemic uptake of HHPA:2AE occurred. However, the possibility that these effects are a consequence of local toxicity, rather than systemic, is acknowledged.

No substance-specific data on inhalation or dermal uptake of HHPA:2AE were identified. However, HHPA:2AE is classified as corrosive to the skin, which may facilitate dermal uptake due to disruption of the barrier function.

Absorption – platinum

The available data on platinum indicate that absorption, even of water soluble Pt compounds, is generally very low following oral exposure. Seventy-one fasted male rats were administered a dose of radiolabelled191Pt (as PtCl4) 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)2were 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.].

Laboratory studies provide only very limited insights into the extent of absorption of Pt 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 hours 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, PtCl4or 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 (or lungs) (Moore et al., 1975a).

REACH guidance states that a reasonable default assumption is normally 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 another soluble platinum salt, dipotassium tetrachloroplatinate, showed a greater degree of absorption [about 5-8%] than this default approach would assume. Using a K2PtCl4solution (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 0.0034 and 0.0005%, respectively (Franken et al., 2015). A slightly earlier publication reported mean skin diffusion and receptor solution percentages of 2.2% and 0.00023%, 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 Pt 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).

Absorption – 2-aminoethanol

2-Aminoethanol “is a normal component of human food. It is part of the membrane-constituting class of glycerophospholipids and a degradation product of the amino acid serine”. There are no substance-specific data on systemic availability following oral or inhalation exposure (OECD, 2016).

In a 2-generation reproductive toxicity study, in which Wistar rats (10/sex/group) received diets containing 0, 100, 300 or 1000 mg “ethanolamine HCl”/kg bw/day for 10 weeks, plasma concentrations of 2-AE increased in a dose-dependent manner. Reported plasma concentrations equated to absorbed doses of < 3 mg 2-AE/kg bw for control animals, < 4, 8-11 and 60-81 mg/kg bw in the low-, mid- and high-dose groups, respectively (Fiume et al., 2015). The figures from the mid- and high-dose groups correspond to approximate absorption values of 2.6

– 8.1%.

"In vitrohuman data indicate that dermal absorption in humans could be low but insufficient information was available to derive a more definitive value" (OECD, 2016). Inin vitrostudies on skin samples from rats, mice, rabbits and humans, undiluted 2-AE was applied to the skin for 6 hours. The cumulative dose absorbed was reported to be 5.98%, 16.92%, 8.66% and 0.61% in the four respective species. Absorption of aqueous 2-AE was 1.32%, 24.79%, 1.87% and 1.11%, respectively. Human skin was the least permeable of the samples examined (Fiume et al., 2015).

Absorption – Key values for CSA

The available data suggest that both Pt and 2-AEare individually poorly absorbed after oral administration; it is currently unknown whether their complexation has any effect on their absorption. Nevertheless, following ECHA guidance and aiming to maintain a suitably health-precautionary figure for use in subsequent risk and exposure assessments, a figure of 0.5% oral absorption has been taken forward, based primarily on the findings for Pt in rats.

Due to the chemical nature of the 2-AE ligand, it is unclear how the available data on other Pt salts correspond to the potential behaviour of this complex. Further, while it is unlikely that exposure to HHPA:2AE via the lungs will occur to any significant extent, ECHA guidance notes "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 for the CSA, so as to result in the most health-precautionary DNEL.

For dermal absorption, the combination of default values and considerations from the data are somewhat conflicting. Absorption in the range indicated by oral studies on Pt (i.e. <1%), as suggested by ECHA guidance and ICMM (2007), seems to be too low when considering thein vitroPt absorption studies on human skin (Franken et al., 2014, 2015), but consistent with levels of absorption seen inin vitrostudies of 2-AE with human skin (Fiume et al., 2015). However, assuming 100% dermal absorption is arguably an overestimation and hence the lower of the two ECHA (2014) default values for dermal absorption, 10%, would seem a more appropriate value for the current safety assessment. However, the potential of HHPA:2AE to disrupt skin barrier function, possibly facilitating increased dermal penetration, cannot be excluded, especially considering its known corrosivity to human skinin vitro. A value of 20% dermal absorption is, therefore, proposed.

Distribution/Metabolism

No information is available on how the HHPA:2AE complex breaks down, but indications from ecotoxicological studies are that it readily separates into dihydrogen hexahydroxyplatinate and 2-aminoethanol in aqueous test media. There are no substance-specific data on whether there is dissociation prior to uptake. Once absorbed, distribution of HHPA and 2-aminoethanol throughout the body is expected based on a relatively low molecular weight (≈ 420 g/mol assuming a 1:2 ratio of HHPA:2AE).

In Moore et al.'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).

No substance-specific data on the tissue distribution of 2-aminoethanol are available. However, adverse toxicological effects on the reproductive system have been reported, indicating that 2-AE or its metabolites does reach these tissues.

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).

No substance-specific data are available on the elimination/excretion of 2-AE.

Conclusion

Experimental data suggest that HHPA:2AE is likely to be poorly absorbed after oral exposure. Although inhalation is not anticipated to be a significant route of exposure, absorption could be extensive. A high dermal bioavailability is unlikely, although the potential for increased percutaneous absorption of HHPA:2AE – classified as corrosive to the skin – as a result of skin barrier disruption is noted.

Absorption values of 0.5%, 100% and 20% for the oral, inhalation and dermal routes, respectively, are proposed for the CSA, and 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 (2017). European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Chapter R.7c: endpoint specific guidance. Version 3.0. June 2017.

Fiume MM, Heldreth BA, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG, Jr., Shank RC, Slaga TJ, Snyder PW and Andersen FA (2015). Safety assessment of ethanolamine and ethanolamine salts as used in cosmetics. International Journal of Toxicology 34 (Suppl 2), 84S-98S.

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.

OECD (2016). Community Rolling Action Plan (CoRAP) Substance Evaluation Report: 2-aminoethanol. Submitting Member State Competent Authority: UK. Version Number: 2. Date: September 2016. https://echa.europa.eu/documents/10162/5ec826b2-37b2-1a35-4f85-4ec844645813

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 according to OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method) ; according to EU Method B.1 tris (Acute Oral Toxicity - Acute Toxic Class Method)	LD50: >2000 mg/kg bw (male/female)	1 (reliable without restriction) key study experimental study **Test material** dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3, (full information in **Annex II**). **Reference** **Antonelli MA 2001**

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: the study does not need to be conducted because the substance is classified as corrosive to the skin [study scientifically not necessary / other information available]

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: the study does not need to be conducted because the substance is classified as corrosive to the skin [study scientifically not necessary / other information available] ; [See below] - This study does not need to be conducted as the substance does not meet the criteria for classification as acutely toxic or as STOT SE by the oral route, in a reliable study (Antonelli, 2001). In addition, significant human exposure via skin contact during production and/or use is unlikely. Finally, for animal welfare reasons, conducting new in

vivo toxicity tests is considered as a last resort. Consequently, in vivo testing by the dermal route 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

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

In an OECD Test Guideline 423 study, to GLP, the acute oral LD50 value of dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) was determined to exceed 2000 mg/kg bw following gavage administration in rats (Antonelli, 2001).

No relevant acute dermal or inhalation toxicity data were identified.

Value used for CSA:
Acute oral toxicity:
no adverse effect observed
Acute dermal toxicity:
no study available
Acute inhalation toxicity:
no study available

Additional information:

No relevant acute toxicity human data were identified.

In an OECD Test Guideline 423 study, to GLP,dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2)was studied for acute toxicity after single oral administration in Sprague-Dawley rats. The test substance was administered by stomach tube (in carboxymethyl cellulose) at a dose of 2000 mg/kg bw to groups of rats (3/sex).No mortality was observed and there were no clinical signs or body weight changes at the end of the 14-day observation period. Subsequent necropsy revealed no gross abnormalities. The acute oral median lethal dose (LD50) of dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) was determined to exceed 2000 mg/kg bw in male and female rats (Antonelli, 2001).

No relevant acute dermal or inhalation toxicity data were identified. However, acute toxicity testing by a second route is not considered appropriate as dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) is considered corrosive to the skin.

Justification for classification or non classification:

Based on the results of the available and reliable acute oral rat study, dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2)does not require classification for acute oral toxicity 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
Coverage: Vehicle: according to OECD Guideline 439 (In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method) ; according to EU Method B.46 (In Vitro Skin Irritation: Reconstructed Human Epidermis Model Test)	Since this test cannot resolve between GHS Categories 1 and 2, further information on skin corrosion will be required to determine the final classification. % tissue viability - Score is a percentage of the negative control mean (42 hour time point). Value: 17.9 (positive indication of irritation - Mean relative viability <=50% the test substance is considered to be irritant to skin..)	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2); dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3, Form: liquid (full information in **Annex II**). **Reference** **Spruth B 2018**

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

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
in vitro study Bovine eyes from cattle (not specified) Vehicle: unchanged (no vehicle) according to OECD Guideline 437 (Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants) [before 26 July 2013] ; according to EU method B.47 (Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants)	No prediction can be made from the available IVIS. in vitro irritation score mean (10 minute time point); value 4.585	1 (reliable without restriction) supporting study experimental study **Test material** Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2); dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3, Form: liquid (full information in **Annex II**). **Reference** **Spruth B 2016**

Data waiving

Information requirement: Eye Irritation

Reason: study scientifically not necessary / other information available

Justification: the study need not be conducted because the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes [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:

In an in vitro EpiDerm skin irritation assay conducted in accordance with OECD guideline 439 and to GLP, dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2) was cytotoxic and, hence, irritant to skin (Spruth, 2016a).

In an in vitro EpiDerm skin corrosion assay conducted in accordance with OECD guideline 431 and to GLP, dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) was corrosive to skin and classified as sub-category 1B-and-1C (Spruth, 2016b).

In an in vitro bovine corneal opacity and permeability (BCOP) assay conducted in accordance with OECD guideline 437, the In Vitro Irritancy Score (IVIS) for dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) was calculated to be 4.585. No classification conclusion concerning irritant or corrosive potential of the test item can be made (Spruth, 2016c).

No relevant respiratory tract irritation data were identified.

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

Additional information:

No relevant human irritation/corrosion data were identified.

Dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) was tested for skin irritation potential in an in vitro reconstructed human epidermis model (EpiDerm assay) conducted in accordance with OECD guideline 439 and to GLP. EpiDerm is a three-dimensional human skin model comprising a reconstructed epidermis with a functional stratum corneum and irritant test materials are identified by their ability to decrease cell viability below defined threshold limits. Cell viability was quantitatively measured using the MTT reduction assay with optical density being expressed as a relative percentage of that of the negative control. If the resulting mean relative viability (as adjusted for intrinsic colour) is less than or equal to 50% of the negative control, the test substance is considered to be irritant to skin. The mean cell viability following 60-minute exposure to the test substance was calculated to be less than 50% (17.9% of the negative controls), and it was therefore considered to be cytotoxic and predicted to be irritant to skin. The positive and negative controls were considered valid. Under the conditions of this assay, dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2) would be classified as “irritant” (Category 2) under GHS classification criteria (Spruth, 2016a). Since this test cannot resolve between GHS Categories 1 and 2, further information on skin corrosion is required to determine the final classification (see below).

Dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) was tested for skin corrosivity potential in an in vitro EpiDerm assay conducted in accordance with OECD guideline 431 and to GLP. Cell viability was quantitatively measured using the MTT reduction assay with optical density being expressed as a relative percentage of that of the negative control. The mean cell viability following exposure to the test substance was calculated to be greater than 50% (51.5% of the negative controls) after a 3-minute exposure and less than 15% (12.8% of the negative controls) after a 1-hour exposure, and it was therefore considered to be corrosive to skin. Under the conditions of this assay, dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) did not meet the criteria for classification as corrosive category 1A under GHS classification

criteria but would be classified as sub-category 1B-and-1C (Spruth, 2016b).

In an in vitro bovine corneal opacity and permeability assay conducted in accordance with OECD guideline 437 and to GLP, dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) was applied to isolated bovine corneas for 10 minutes, followed by an incubation period of 120 minutes. The IVIS calculated from individual scores for induced opacity (decreased light transmission through the cornea) and permeability (passage of sodium fluorescein dye through the cornea) was 4.585, which is above the cut-off value of 3 (no category) and below the cut-off value of 55 (identifying test substances as inducing serious eye damage). Hence, no classification conclusion concerning irritant or corrosive potential of the test item can be made (Spruth, 2016c). Substances that are corrosive to the skin are considered as leading to serious damage to the eyes. Consequently, no further testing is necessary and dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) should be classified for eye effects in Category 1 according to EU CLP criteria (EC 1272/2008).

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 in vitro skin corrosion study, dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) should be classified as corrosive to the skin (category 1B) according to EU CLP criteria (EC 1272/2008).

According to ECHA guidance on the application of CLP criteria (ECHA, 2017b), “if a substance or mixture is classified as Skin corrosive Category 1 then serious damage to eyes is implicit…thus, the corrosive substance or mixture is also classified, but the corresponding hazard statement is not indicated on the label and there is no need to proceed with classification for eye effects”. HHPA:2AE is classified for skin effects as corrosive sub-category 1B. Consequently, the compound is classified for eye effects in Category 1 under EU CLP.

5.4. Corrosivity

5.4.1. Non-human information

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

Table 5.4. Studies on skin irritation related to corrosivity

Method	Results	Remarks
Tissue studied: skin corrosion: in vitro / ex vivo Coverage: Vehicle: according to OECD Guideline 431 (In Vitro Skin Corrosion: Human Skin Model Test) [before 26 Sept. 2014]	Sub-category 1B-and-1C since this test cannot resolve between the two % tissue viability - Score is a percentage of the negative control mean (3 minute time point). Value: 51.5 (possible indication of corrosivity - Mean relative viability <=50% the test substance is considered to be corrosive to skin (classified as sub-category 1A)) mean (1 hour time point). Value: 12.8	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2); dihydrogen hexahydroxyplatinat

	(positive indication of corrosivity - Mean relative viability >=50% (after 3 minutes) and <15% (after 1 hour) the test substance is considered to be corrosive to skin (classified as sub-category 1B-and-1C))	e(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3, Form: liquid (full information in **Annex II**). **Reference** **Spruth B 2016**

5.4.2. Human information

No relevant information available.

5.4.3. Summary and discussion of corrosion

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 5.5. Studies on skin sensitisation

Method	Results	Remarks
mouse (CBA [mouse]) female skin sensitisation: in vivo (LLNA) according to OECD Guideline 442B (Skin Sensitization: Local Lymph Node Assay: BrdU-ELISA) ; according to EC method B.51. Skin Sensitisation: Local Lymph Node Assay: BrdU-ELISA	GHS criteria not met Stimulation index: (The stimulation indices were 1.040, 0.835 and 0.815 at concentrations of 10, 25 and 50% w/w, respectively.) disintegrations per minute (DPM): (Not applicable)	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2); dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3, Form: liquid (full information in **Annex II**). **Reference** **Haferkorn J 2016**

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

No relevant information available.

5.5.2. Respiratory system

5.5.2.1. Non-human information

No relevant information available.

5.5.2.2. Human information

No relevant information available.

5.5.3. Summary and discussion of sensitisation

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

Skin sensitisation

In a GLP mouse local lymph node assay (LLNA): BrdU-ELISA, conducted accroding to OECD guideline 442B, dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) was not sensitising (Haferkorn, 2016).

No respiratory tract sensitisation data are available.

Value used for CSA: no adverse effect observed (not sensitising)
Additional information:

No relevant human skin sensitisation data were identified. No in vitro skin sensitisation studies were identified, or are required, as a reliable in vivo study is already available.

The skin sensitising potential of dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) has been assessed in a GLP mouse LLNA: BrdU-ELISA, conducted according to OECD Test Guideline 442B. Following a preliminary range-finding study to assess irritancy, female CBA mice (5/group) were treated topically with 0, 10, 25 or 50% dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2) (in propylene glycol) on three consecutive days (1, 2 and 3). On day 6, cell proliferation in the local lymph nodes was measured by incorporation of injected 5-bromo-2-deoxyuridine (BrdU) using ELISA. No mortality or clinical signs of toxicity were observed, and there were no signs of local irritation, as measured by ear weight or thickness differences, at the application site. Very slight erythema was observed in 3 animals at the highest tested concentration, compared to well-defined erythema in all positive control animals. Observed stimulation index

values were 1.040, 0.835 and 0.815 at concentrations of 10, 25 and 50% w/w, respectively. Hence, the stimulation indices of the test item treated groups calculated for the BrdU labelling index did not exceed the threshold value of 1.6. Positive and vehicle controls performed as expected. Therefore, under the conditions of this study, dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2) does not require classification for skin sensitisation (Haferkorn, 2016).

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

Respiratory sensitisation

Value used for CSA: no study available
Additional information:

No respiratory tract sensitisation data are available. A new study was not conducted as no standard and validated test method is available and it is not a REACH Standard Information Requirement.

Justification for classification or non classification:

Based on the results of the available and reliable murine LLNA assay, dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) does not warrant classification for skin sensitisation, according to EU CLP criteria (EC 1272/2008).

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 5.6. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks
rat [common rodent species] (Crj: CD(SD) [rat]) male/female repeated dose toxicity: oral, other - Part of a combined repeated dose study (OECD 422) with reproductive and developmental toxicity screening. (oral: gavage) 0mg/kg bw/day (actual dose received) 100mg/kg bw/day (actual dose received) 300mg/kg bw/day (actual dose received) 1000mg/kg bw/day (actual dose	NOAEL - general (systemic) toxicity: 300 mg/kg bw/day (actual dose received) (male/female) based on: (test mat.) clinical signs - Slight to pronounced salivation and reduced motility ; body weight and weight gain - Slight reductions in body weight ; food consumption and compound intake - Slight reductions in food intake	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2); dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3,

received) Vehicle: corn oil Exposure: Males: 2 weeks prior to mating (test days 15-29), during the mating period (maximum test days 30-43) and until test day 50. Females: 2 weeks prior to mating (test days 15-29), during the mating period (maximum test days 30-43) and during the lactation period until test days 64-77 (corresponding to lactation days 13-15). (Once daily.) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)		Form: liquid (full information in **Annex II**). **Reference** **Hansen B 2017**

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 422 combined repeated dose and reproduction/developmental toxicity screening study in rats, conducted to GLP, dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, was administered by gavage for at least 28 days at doses of 0, 100, 300 or 1000 mg/kg bw/day. Control animals received vehicle only. Treatment-related adverse effects were observed in the high dose animals (including reduced motility, decreased food consumption and body weight). The NOAEL for systemic toxicity was established as 300 mg/kg bw/day (Hansen, 2017).

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: 300mg/kg bw/day; subacute, rat [common rodent species])

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

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

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

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

Additional information:

No relevant human data were identified.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, CD rats (10/sex/group) were orally administered dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol by stomach tube (gavage, in corn oil) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for at least 28 days (14 days pre-mating, as well as during the mating and post-mating periods). Females were dosed for 14 days pre-mating, through mating, gestation (around 22 days) and up to post-natal day 13 (50 -63 days in total). Control animals received vehicle only. In the high-dose group, animals demonstrated clinical signs of toxicity including salivation, breathing sounds and reduced motility, as well as decreased food consumption and body weight. Gross lesions to the stomach were also observed and confirmed by further microscopic examination, but might have arisen due to deposition of the test item and were not considered as an adverse effect of the test item. On this basis, the NOAEL for systemic toxicity was established as 300 mg/kg bw/day (Hansen, 2017).

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:

In a reliable repeated dose toxicity study (combined with a reproductive/developmental screening assay) involving gavage administration of dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol to rats for at least 28 days, no adverse systemic effects were seen at up to 300 mg/kg bw/day. As such, classification of this substance as STOT-RE is not required, according to EU CLP criteria (EC 1272/2008).

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 5.7. In vitro genotoxicity studies:

Method	Results	Remarks
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.) E. coli WP2 uvr A [bacteria] (with and without met. act.) Test concentrations: Two main experiments. In the first, using the plate incorporation method, the test substance was assayed at 313, 625, 1250, 2500 or 5000 ug/plate in all five tester strains, in the absence or presence of S9. In the second, TA98, TA100, and WP2 uvrA strains were tested under the same experimental conditions as the first experiment, while for TA1535 and TA1537, a pre-incubation step was included. Positive control substance(s): sodium azide Positive control substance(s): 9-aminoacridine Positive control substance(s): 2-nitrofluorene Positive control substance(s): 2-Aminoanthracene in DMSO Positive control substance(s): methylmethanesulfonate according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria] ; according to EU Method B.13/14 (Mutagenicity - Reverse Mutation Test Using Bacteria) [in vitro gene mutation study in bacteria]	Test results: positive for S. typhimurium, other: TA98, TA100 [bacteria]; met. act.: with and without genotoxicity: positive cytotoxicity: no cytotoxicity nor precipitates, but tested up to recommended limit concentrations vehicle controls valid: valid negative controls valid: valid positive controls valid: valid Test results: positive for E. coli WP2 uvr A [bacteria]; met. act.: with and without genotoxicity: positive cytotoxicity: no cytotoxicity nor precipitates, but tested up to recommended limit concentrations vehicle controls valid: valid negative controls valid: valid positive controls valid: valid Test results: positive for S. typhimurium TA 1537 [bacteria]; met. act.: with and without genotoxicity: positive cytotoxicity: no cytotoxicity nor precipitates, but tested up to recommended limit concentrations vehicle controls valid: valid negative controls valid: valid positive controls valid: valid	1 (reliable without restriction) key study experimental study **Test material** dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3, (full information in **Annex II**). **Reference** **Scarcella O 2001**
mammalian cell gene mutation assay [gene mutation] (in vitro gene mutation study in mammalian cells - Type of genotoxicity: gene mutation) Chinese hamster lung fibroblasts (V79) [mammalian cell line] (with and without met. act.) Test concentrations: Concentrations of 2.44, 4.88, 9.77, 19.5, 39.1 and 78.1 ug/ml were used in the absence of S9, and 313, 625, 1250, 2500 and 5000 ug/ml in the presence of S9. Positive control substance(s): ethylmethanesulphonate	Test results: positive for Chinese hamster lung fibroblasts (V79) [mammalian cell line]; met. act.: with and without genotoxicity: positive cytotoxicity: cytotoxicity - see below vehicle controls valid: valid negative controls valid: positive controls valid: valid	1 (reliable without restriction) key study experimental study **Test material** dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3, (full information in **Annex II**).

Positive control substance(s): 7,12-dimethylbenzanthracene according to OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) [in vitro gene mutation study in mammalian cells]		**Reference** **Cinelli S 2002**

Data waiving

Information requirement: In vitro genotoxicity: (in vitro cytogenicity / chromosome aberration study in mammalian cells)

Reason: study scientifically not necessary / other information available

Justification: see 'Remark' - No mammalian cell cytogenicity data are available for dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2). Irrespective of the result of any hypothetical cytogenicity test, the observation of mutagenic activity in bacterial (Scarcella, 2001) and mammalian cells (Cinelli, 2002) necessitates the consideration of further in vivo testing. Related platinum compounds have also demonstrated a general tendency to induce genotoxicity in vitro; no adequate in vivo genotoxicity data were identified for any of these substances. Additional in vivo testing of other platinates has been proposed to clarify the relevance of the in vitro findings. Consequently, it is considered unnecessary to conduct further in vitro testing on dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2). Instead, further in vivo genotoxicity testing has been performed.

5.7.1.2. In vivo data

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

Table 5.8. 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 500mg/kg bw/day (actual dose received) 1000mg/kg bw/day (actual dose received) 2000mg/kg bw/day (actual dose received) Cyclophosphamide. - Route of administration: Gavage. - Doses / concentrations: A single dose of 19 mg/kg bw, dissolved in physiological saline. according to OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus]	Genotoxicity: negative (male) toxicity: no effects vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, (full information in **Annex II**). **Reference** **Eurlings IMJ 2020**
Justification for type of information: An EPMF member company received an official request from the Korean authorities to perform the in vivo mutagenicity assay with hexahydroxyplatinate,compound with 2-aminoethanol(1:2) (CAS 68133-90-4), ahead of the formal testing proposal approval by ECHA. The requested		

experimental information is in line with the assay submitted in the TP for this substance. The deadline given by the Korean authorities was however much tighter than the anticipated date of receiving the final decision on the TP. Therefore, the in vivo mutagenicity testing with this substance has been initiated in the EU prior to receiving the final decision on the TP. In the attached document (translation from Korean and anonymised), a justification for initiating the in vivo muta testing upon official request from an non-EU authority (i.e. request outside EU-REACH), ahead of receiving the final decision on the TP. More information is available upon request.		
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 500mg/kg bw/day (actual dose received) 1000mg/kg bw/day (actual dose received) 2000mg/kg bw/day (actual dose received) Ethyl methanesulphonate. - Route of administration: Gavage. - Doses / concentrations: 200 mg/kg bw, dissolved in physiological saline, administered twice. according to 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. (male) toxicity: no effects vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Liver: no statistically significant increase in % tail intensity. (male) toxicity: not examined vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Glandular stomach: no statistically significant increase in % tail intensity. (male) toxicity: not examined vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark: Genotoxicity: negative - Duodenum: no statistically significant increase in % tail intensity. (male) toxicity: not examined vehicle controls valid: valid negative controls valid: positive controls valid: valid Remark:	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, (full information in **Annex II**). **Reference** **Eurlings IMJ 2020**
Justification for type of information: An EPMF member company received an official request from the Korean authorities to perform the in vivo mutagenicity assay with hexahydroxyplatinate,compound with 2-aminoethanol(1:2) (CAS 68133-90-4), ahead of the formal testing proposal approval by ECHA. The requested experimental information is in line with the assay submitted in the TP for this substance. The deadline given by the Korean authorities was however much tighter than the anticipated date of receiving the final decision on the TP. Therefore, the in vivo mutagenicity testing with this substance has been initiated in the EU prior to receiving the final decision on the TP. In the attached document (translation from Korean and anonymised), a justification for initiating the in vivo muta testing upon official request from an non-EU authority (i.e. request outside EU-REACH), ahead of receiving the final decision on the TP. More information is available upon request.		

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):

In a bacterial reverse mutation (Ames) test, conducted according to OECD Test Guideline 471 and to GLP, dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) induced reverse mutations in strains of Salmonella typhimurium and Escherichia coli both in the absence and presence of a rat liver metabolic activation system (S9) (Scarcella, 2001).

In an in vitro mammalian cell gene mutation assay, conducted in accordance with OECD Test Guideline 476 and to GLP, dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) induced mutations in Chinese hamster V79 cells when tested both with and without S9 (Cinelli, 2002).

No mammalian cell cytogenicity data are available for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2). Further in vitro testing in considered unnecessary in the light of the proposed in vivo genotoxicity testing.

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 dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, 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 500, 1000 or 2000 mg/kg bw/day of the test item on three consecutive days. 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 evidence of an increase in the incidence of micronucleated polychromatic erythrocytes. There was no increase in % tail intensity in the liver, glandular stomach, kidney or duodenum (Eurlings, 2020). As such, and as platinum was detected in the plasma of the test animals, the test item was considered 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, dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) 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).

Additional information:

In an OECD Test Guideline 471 study, conducted according to GLP, dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) was assessed for its ability to induce gene mutations in strains of S. typhimurium (TA1535, TA1537, TA98, TA100) and E. coli (WP2 uvrA). The test was performed in two independent experiments (involving the plate incorporation method, including a pre-incubation step for TA1535 and TA1537 in Experiment 2), with dose levels of up to 5000 µg/plate (determined following an initial toxicity test), both in the absence and presence of S9 using liver fraction from rats pre-treated with phenobarbitone and beta-naphthoflavone. In experiment 1, dose-related increases in revertant numbers, which were at least two-fold

the control values, were observed in WP2 uvrA both with and without S9. The test item induced reproducible, large and dose-related increases in the number of revertant colonies, which were more than two-fold the control values, with TA98, TA100 and WP2 uvrA tester strains in the plate incorporation assays, at the higher dose levels both in the presence and absence of S9 metabolism. Increases in revertant numbers were also observed with TA1537 in the pre-incubation assay. These increases were greater than twice the control value at non-toxic dose-levels, both in the presence and absence of S9 metabolism. It was concluded that dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) was mutagenic in S. typhimurium and E.coli under the reported experimental conditions (Scarcella, 2004).

In an in vitro GLP study, conducted in accordance with OECD Test Guideline 476 (in vitro mammalian cell gene mutation assay), dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) was tested for its ability to induce 6 -thioguanine resistant mutants in Chinese hamster V79 cells. Cells were exposed to test material for 3 hours, both in the presence and absence of metabolic activation using liver S9 fraction from rats pre-treated with phenobarbitone and betanaphthoflavone. On the basis of a preliminary cytotoxicity test, the maximum dose levels for the mutation assay were selected as 78.1 and 5000 µg/ml for treatment in the absence or presence of S9, respectively. Dose related and significant increases in mutant numbers or mutant frequency were observed following treatment with the test item, in the absence and presence of S9 metabolism. These increases were greater than five-fold the spontaneous mutation frequency, in replicate cultures at both expression times (days, 6 and 8). It was concluded that dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) was mutagenic in Chinese hamster V79 cells, both in the presence and absence of S9 (Cinelli, 2002).

In a combined in vivo micronucleus test and Comet assay in rats, dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, administered by gavage at doses of 500, 1000 or 2000 mg/kg bw/day for three days did not cause an increased incidence of micronucleated polychromatic erythrocytes. Treatment also gave no evidence of DNA damage in the liver, kidney, glandular stomach or duodenum when assessed by the Comet procedure. As such, the test item was considered to be non-genotoxic in vivo (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 (DECOS, 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 (DECOS, 2008). Limited experimental data on carcinogenicity for other platinum compounds give no evidence of activity that would meet classification criteria (DECOS, 2008; SCOEL, 2011).

Following 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) and the unclear in vivo relevance of these in vitro findings, a combined in vivo micronucleus test and Comet assay in rats (with dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol) did not cause an increased incidence of micronucleated polychromatic erythrocytes and gave no evidence of DNA damage in the liver, kidney, glandular stomach or duodenum when assessed by the Comet procedure (Eurlings, 2020).

References

DECOS (2008). Dutch Expert Committee on Occupational Standards. Platinum and Platinum Compounds.

Health-based recommended occupational exposure limit. Gezondheidsraad, 2008/12OSH. https://www.gezondheidsraad.nl/en/publications/gezonde-arbeidsomstandigheden/platinum-and-platinum-compounds-health-based-recommended

EMA (2008). European Medicines Agency. Guideline on the specification limits for residues of metal catalysts or metal reagents. Committee for Medicinal Products for Human Use (CHMP). EMEA/CHMP/SWP/4446/2000. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003586.pdf

SCOEL (2011). Recommendation from the Scientific Committee on Occupational Exposure Limits for platinum and platinum compounds. SCOEL/SUM/150. http://ec.europa.eu/social/BlobServlet?docId=7303&langId=en

WHO (1991). World Health Organization. Platinum. International Programme on Chemical Safety. Environmental Health Criteria 125. http://www.inchem.org/documents/ehc/ehc/ehc125.htm#SectionNumber:7.4

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.

5.9. 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 5.9. Studies on fertility

Method	Results	Remarks
rat (Crj: CD(SD) [rat]) male/female screening for reproductive / developmental toxicity - Part of a combined repeated dose study (OECD 422) with reproductive and developmental toxicity screening. oral: gavage 0mg/kg bw/day (actual dose received) Vehicle control 100mg/kg bw/day (actual dose received) "low dose" 300mg/kg bw/day (actual dose received) "intermediate dose" 1000mg/kg bw/day (actual dose received) "high dose" Vehicle: corn oil Exposure: Males: 2 weeks prior to mating (test days 15-29), during the mating period (maximum test days 30-43) and until test day 50. Females: 2 weeks prior to mating (test days 15-29), during the mating period (maximum test days 30-43) and during the lactation period until test days 64-77 (corresponding to lactation days 13-15). (Once daily) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	**First parental generation (P0)** NOAEL - Fertility and reproductive parameters (PO) 1000 mg/kg bw/day (actual dose received)) (male/female) based on: No reproductive effects seen at highest tested dose **F1 generation** NOAEL - adverse effects on prenatal development (conceptus to birth) : 1000 mg/kg bw/day (actual dose received) (male/female) based on: No effects seen at highest tested dose NOAEL - adverse effects on postnatal development (pup) : 1000 mg/kg bw/day (actual dose received) (male/female) based on: No effects seen at highest tested dose **Overall reproductive toxicity** no Lowest effective dose / concentration Relation to other toxic effects:	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2); dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3, Form: liquid (full information in **Annex II**). **Reference** **Hansen B 2017**

Toxicity to reproduction: other studies

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

No relevant information available.

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 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol was administered by gavage for at least 28 days at doses of 0, 100, 300 or 1000 mg/kg bw/day. No effects on any measured reproductive or fertility parameters were observed. The reproductive NOAEL was the highest tested dose (1000 mg/kg bw/day) (Hansen, 2017).

Value used for CSA (route: oral):
no adverse effect observed (NOAEL): 1000mg/kg bw/day (subacute, rat [common rodent species])

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

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

Additional information:

No relevant data in humans were identified.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, CD rats (10/sex/group) were orally administered dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol by stomach tube (gavage, in corn oil) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for at least 28 days (14 days pre-mating, as well as during the mating and post-mating periods). Females were dosed for 14 days pre-mating, through mating, gestation (around 22 days) and up to post-natal day 13 (50 -63 days in total). Control animals received vehicle only. There were no test item-related adverse effects on the measured reproductive parameters (fertility index, gestation index, precoital time and gestation length). Consequently, the NOAEL for reproductive toxicity was set at 1000 mg/kg bw/day, the highest dose tested (Hansen, 2017).

Developmental toxicity

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

In an OECD Test Guideline 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol for at least 28 days, no effects on pre- or postnatal development of pups were observed. The pre- and postnatal developmental NOAELs were set at 1000 mg/kg bw/day, the highest tested dose (Hansen, 2017).

Value used for CSA (route: oral):
no adverse effect observed (NOAEL): 1000mg/kg bw/day (subacute; rat [common rodent species])

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

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

Additional information:

No relevant data in humans were identified.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, CD rats (10/sex/group) were orally administered dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol by stomach tube (gavage, in corn oil) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for at least 28 days (14 days pre-mating, as well as during the mating and post-mating periods). Females were dosed for 14 days pre-mating, through mating, gestation (around 22 days) and up to post-natal day 13 (50 -63 days in total). Control animals received vehicle only. There were no test item-related adverse effects on the pre-natal (pre- and post-implantation loss, number of pups born, number of stillbirths, birth and live birth indices) or the post-natal (pup body weight, survival index, the endocrine/sexual development (T4 levels, ano-genital distance, male nipples counting), gross abnormalities) development of the pups. Consequently, the NOAELs for effects on pre- and postnatal development were set at 1000 mg/kg bw/day, the highest dose tested (Hansen, 2017).

Justification for classification or non classification:

In a reliable combined repeated dose toxicity study and reproductive/developmental toxicity screening study involving gavage administration of dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol to rats for at least 28 days, no adverse effects on reproductive parameters (sexual function or fertility) or development of offspring were seen at up to 1000 mg/kg bw/day. As such, classification of this substance for reproductive toxicity 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.

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

5.11.1. Overview of typical dose descriptors for all endpoints

Table 5.10. 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	no adverse effect observed
Acute toxicity	dermal	no study available
Acute toxicity	inhalation	no study available
Irritation / Corrosivity	skin	adverse effect observed (corrosive)
Irritation / Corrosivity	eye	adverse effect observed (irreversible damage)
Irritation / Corrosivity	resp. tract	no study available
Sensitisation	skin	no adverse effect observed (not sensitising)
Sensitisation	resp. tract	no study available
Repeated dose toxicity	oral	adverse effect observed (NOAEL): 300mg/kg bw/day (subacute; rat [common rodent species])
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	no adverse effect observed (NOAEL): 1000mg/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): 1000mg/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 5.11. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.023mg/m³	repeated dose toxicity (Oral)
Inhalation	Systemic effects - Acute	no hazard identified	
Inhalation	Local effects - Long-term	medium hazard (no threshold derived)	skin irritation/corrosion
Inhalation	Local effects - Acute	medium hazard (no threshold derived)	skin irritation/corrosion
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.016mg/kg bw/day	repeated dose toxicity (Oral)
Dermal	Systemic effects - Acute	no hazard identified	
Dermal	Local effects - Long-term	medium hazard (no threshold derived)	skin irritation/corrosion
Dermal	Local effects - Acute	medium hazard (no threshold derived)	skin irritation/corrosion
Eyes	Local effects	medium hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEC

The DNEL is expressed in Pt as this is what is being measured in the workplace and used in the exposure assessment.

The DNEL for HHPA-2AE is 0.14 mg/m3.

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

Overall Assessment Factor: 75

AF for dose response relationship: 1 (Default ECHA AF; NOAEL from a well-conducted combined repeated-dose with reproductive/developmental toxicity screening study, conducted by the oral route; the NOAEL was set at 300 mg HHPA-2AE/kg bw/day.)

AF for difference in duration of exposure: 6 (Default ECHA AF for subacute (28-day) to chronic extrapolation.)

AF for interspecies differences (allometric scaling): 1 (Default ECHA AF for rat for toxicokinetic differences in metabolic rate (allometric scaling) is not required.)

AF for other interspecies differences: 2.5 (Default ECHA AF for remaining toxicokinetic differences (not related to metabolic rate) and toxicodynamic differences.)

AF for intraspecies differences: 5 (Default ECHA AF for (healthy) worker.)

AF for the quality of the whole database: 1 (Default ECHA AF; the human health effects data are reliable and consistent, and confidence in the database is high.)

AF for remaining uncertainties: 1 (Not requried.)

Further explanation on hazard conclusions:

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

Inhalation Systemic effects - Acute

Inhalation Local effects - Long-term

Inhalation Local effects - Acute

Dermal Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEL

The DNEL is expressed in Pt as this is what is being measured in the workplace and used in the exposure assessment.

The DNEL for HHPA-2AE is 0.1 mg/kg bw/day.

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

Overall Assessment Factor: 75

AF for dose response relationship: 1 (Default ECHA AF; NOAEL from a well-conducted combined repeated-dose with reproductive/developmental toxicity screening study, conducted by the oral route; the NOAEL was set at 300 mg HHPA-2AE/kg bw/day.)

AF for difference in duration of exposure: 6 (Default ECHA AF for subacute (28-day) to chronic

extrapolation.)

AF for interspecies differences (allometric scaling): 1 (Default ECHA AF for rat for toxicokinetic differences in metabolic rate (allometric scaling) is not required.)

AF for other interspecies differences: 2.5 (Default ECHA AF for remaining toxicokinetic differences (not related to metabolic rate) and toxicodynamic differences.)

AF for intraspecies differences: 5 (Default ECHA AF for (healthy) worker.)

AF for the quality of the whole database: 1 (Default ECHA AF; the human health effects data are reliable and consistent, and confidence in the database is high.)

AF for remaining uncertainties: 1 (Not required.)

Further explanation on hazard conclusions:

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

Dermal Systemic effects - Acute

Dermal Local effects - Long-term

Dermal Local effects - Acute

Discussion:

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

As no relevant data on effects of repeated inhalation exposure of humans or laboratory animals to HHPA:2AE are available, route-to-route extrapolation to calculate an inhalation DNEL from a reliable combined repeated-dose with reproductive/developmental toxicity screening by the oral route was considered a suitable alternative method (particularly as first pass effects are not expected to be significant for this essentially inorganic compound).

In the combined study (OECD Test Guideline [TG] 422), conducted to GLP, HHPA:2AE was administered to rats by gavage for 36 days (in males) and 50-63 days (in females) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Treatment-related adverse effects were observed in the high dose animals (including “slight to pronounced salivation”, slightly reduced motility, and decreased food consumption, body weight and body weight gain). No effects on reproductive parameters, indications of maternal/foetal toxicity, or developmental effects were observed at any dose level. The NOAELs for reproductive (fertility) effects in parental animals and for pre- and post-natal developmental effects in the pups were set at 1000 mg/kg bw/day, the highest dose tested. The NOAEL for general systemic toxicity was set at 300 mg/kg bw/day (Hansen, 2017). These equate to NOAELs of 164.8 and 49.4 mg/kg bw/day, respectively, when expressed as elemental platinum based Pt content of the test substance. T

he tested HHPA:2AE had an elemental platinum content of 16.48%.

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, PtCl4or 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 (or lungs) (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 PtCl4was absorbed (Moore et al., 1975b,c). Similar results were obtained when Pt(SO4)2was administered orally to mice (Lown et al., 1980). The reported maximum plasma 2-AE concentration after oral administration of 0, 100, 300 or 1000 mg 2-AE/kg bw/day (as part of a 2-generation reproduction toxicity study) equated to 81 mg/kg bw in animals administered the highest dose; the overall range of plasma concentrations indicated an absorption of 2.6 – 8.1% (Fiume et al., 2015).

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, based on the laboratory study of Pt salts 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).

Expressed as HHPA:2AE, the corrected inhalatory NOAEC (worker, 8 h exposure/day) = oral NOAEL*(1/sRv[rat])*(ABS[oral-rat]/ABS[inh-human]) *(sRV[human]/wRV) = 300 mg/kg bw/day*(1/0.38 m3/kg bw/day)*(0.5/100)*(6.7 m3 [8h]/10 m3 [8h]) = 2.644 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, 2012). 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 = 2.644*4 = 10.6 mg/m3.

Application of the assessment factors (overall AF 75, described above) to this corrected inhaled NOAEC gives a systemic long-term inhalation DNEL for HHPA:2AE of 0.14 mg/m3, which equates to an elemental platinum exposure of 0.023 mg/m3(23.1 µg/m3).

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 identifiedandthere 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 HHPA:2AE. In a guideline (OECD TG 423, acute toxic class method) acute oral toxicity study in rats (3/sex/group), no mortality or clinical signs of toxicity were apparent in animals given a single dose of 2000 mg/kg bw and observed for 14 days. Consequently the LD50was determined to be in excess of this limit dose and that HHPA:2AE does not require classification for its acute oral toxicity.

"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, 2016a). However, HHPA:2AE is not classified for acute toxicity according to CLP, so a qualitative assessment is not required.

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

There are no data in relation to respiratory tract irritation or sensitisation of HHPA:2AE in humans or laboratory animals. Consequently, no worker-DNELs for long-term or acute local effects in the respiratory tract have been calculated.

The compound is not considered a significant skin sensitiser based on a local lymph node assay in mice (Haferkorn, 2016) [see 'Hazard via dermal route: local effects following long-term or acute exposure' for more detailed discussion of this study].

HHPA:2AE is classified as corrosive to the skin (Category 1B) on the basis of an EpiDerm skin corrosion study (Spruth, 2016a) [see 'Hazard via dermal route: local effects following long-term or acute exposure' for more detailed discussion of this study]. Despite the lack of respiratory tract irritation data, it would appear prudent to assume that this substance would also irritate the respiratory tract if inhaled at sufficient levels/durations. According to ECHA (2016a) guidance "substances classified for skin corrosion Category 1B/1C in CLP" or "Serious eye damage Category 1 in CLP "… "which relate to corrosive or severe irritant effects to the eye or irritant effects to the eyes, respiratory tract and skin simultaneously, are allocated to the moderate hazard band on the basis that exposure to such corrosives, eye damaging or irritant substances should be well-controlled". Therefore, consider recommended Risk Management Measures/Operational Conditions (RMMs/OCs) in Table E.3-1 of ECHA (2016a).

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

As no relevant data on effects of repeated dermal exposure of humans or laboratory animals to HHPA:2AE are available, route-to-route extrapolation to calculate a dermal DNEL from the combined repeated-dose with reproductive/developmental toxicity screening study by the oral route was considered a suitable alternative method (particularly as first pass effects are not expected to be significant for an essentially inorganic compound). This study has been described in detail above ["Hazard via inhalation route: systemic effects following long-term exposure"] (Hansen, 2017).

The oral NOAEL of 300 mg/kg bw/day, based on the observation of signs of toxicity (including reduced

motility, decreased body weight, decreased body weight gain and food consumption), was taken as the health-precautionary critical point of departure for calculating the long-term systemic dermal DNEL for HHPA:2AE. No adverse effects on reproduction (fertility), or on pre- or post-natal development of pups, were reported. This figure equates to a NOAEL of 49.4 mg/kg bw/day for elemental platinum (based on Pt content in the test substance).

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 et al., 1975b,c). The default assumption in the REACH guidance is that dermal absorption will not be higher than by the oral route (ECHA, 2012).

However, twoin vitropermeation studies on a related soluble platinum salt, dipotassium tetrachloroplatinate, indicated a greater degree of dermal absorption [about 5-8%] than this default process would assume. Using a K2PtCl4solution (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.

Inin vitrostudies of 2-AE on skin samples from rats, mice, rabbits and humans, undiluted 2-AE was applied to the skin for 6 hours. The cumulative dose absorbed was reported to be 5.98%, 16.92%, 8.66% and 0.61% in the four respective species. Absorption of aqueous 2-AE was 1.32%, 24.79%, 1.87% and 1.11%, respectively. Human skin was the least permeable of the samples examined (Fiume et al., 2015).

In the absence of high-quality data for dermal absorption, default guidance allows for the estimation of dermal absorption based on other relevant available information (mainly water solubility, molecular weight and log Pow) and expert judgement. HHPA:2AE is prepared and marketed in aqueous solution, and therefore may be able to cross the lipid-rich environment of the stratum corneum to a "low to moderate" extent. Specific expert guidance on the health risk assessment of metals indicates that considerations based on physico-chemical properties do not apply to these substances ("as 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).

Experimental dermal penetration data (human in vitro studies) for a chloroplatinate substance indicated about 5-8% dermal absorption, with values of 0.61 or 1.11% for similar studies using 2-AE. Therefore, the lower of the two ECHA (2014) default values for dermal absorption, 10%, would seem an appropriate value for the current safety assessment. However, the potential of HHPA:2AE to disrupt skin barrier function, possibly facilitating increased dermal penetration, cannot be excluded, especially considering its known corrosivity to human skin in vitro. A value of 20% dermal absorption is, therefore, proposed.

Dose descriptor starting point (after route to route extrapolation) = NOAEL*(ABS[oral-rat]/ABS[der-human]) = 300 mg/kg bw/day*(0.5%/20%) = 7.5 mg/kg bw/day.

Application of the assessment factors (overall AF 75) described above to this corrected dermal NOAEL gives a systemic long-term dermal DNEL for HHPA:2AE of 0.1 mg/kg bw/day, which equates to a platinum exposure of 0.016 mg/kg bw/day (16.5 µg/kg bw/day).

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

Two reliablein vitroEpiDerm studies of HHPA:2AE's skin corrosion/irritation potential have been carried out.

In the first study, conducted according to OECD TG 439, HHPA:2AE displayed a mean cell viability of less than 50% (17.9%) and was hence considered to be irritant to skin (Spruth, 2016b). In a further study, conducted according to OECD TG 431, the mean cell viability following exposure to HHPA:2AE was calculated to be greater than 50% (51.5%) after a 3-minute exposure and less than 15% (12.8%) after a 1-hour exposure, and it was therefore considered to be corrosive to skin (Spruth, 2016a). On this basis, HHPA:2AE is classified as corrosive to the skin (CLP category 1B).

In another guideline (OECD TG 442B) study, HHPA:2AE failed to induce skin sensitisation in the mouse local lymph node assay (LLNA) when tested at concentrations of up to 50% (Haferkorn, 2016). Consequently, the compound is not classified for skin sensitisation under CLP.

No dose-response data was available from which to derive a DNEL, therefore a qualitative assessment was considered appropriate. On the basis of the observed skin corrosivity (category 1B), the substance would be considered in the moderate hazard band according to ECHA (2016a) guidance. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2016a).

Hazard for the eyes

In a bovine corneal opacity and permeability (BCOP) study (OECD TG 437) the irritancy score was calculated to be 4.6 (a score > 55 represents an ocular corrosive and a score ≤ 3 represents a substance for which classification is not required). Hence no classification conclusion concerning irritant or corrosive potential of the test item can be made (Spruth, 2016c).

According to ECHA guidance on the application of CLP criteria (ECHA, 2017), "if a substance or mixture is classified as Skin corrosive Category 1 then serious damage to eyes is implicit…thus, the corrosive substance or mixture is also classified, but the corresponding hazard statement is not indicated on the label and there is no need to proceed with classification for eye effects". HHPA:2AE is classified for skin effects as corrosive sub-category 1B. Consequently, the compound is classified for eye effects in Category 1 under EU CLP. No dose-response data was available from which to derive a DNEL, therefore a qualitative assessment was considered appropriate. Substances classified for serious eye damage (Category 1 in CLP) should be allocated to the "moderate hazard band on the basis that exposure to such corrosives, eye damaging or irritant substances should be well-controlled". Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2016a).

Table 5.12. Hazard conclusions for the general population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects -	hazard unknown but no further	

	Long-term	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

Inhalation Systemic effects - Acute

Inhalation Local effects - Long-term

Inhalation Local effects - Acute

Dermal Systemic effects - Long-term

Dermal Systemic effects - Acute

Dermal Local effects - Long-term

Dermal Local effects - Acute

Oral Systemic effects - Long-term

Oral Systemic effects - Acute

Discussion:

DNELs have been derived only for workers, not for consumers/general population. No uses have been identified in which consumers are exposed to HHPA:2AE. In all uses with potential consumer exposure due to service life of articles, HHPA:2AE 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 forHHPA:2AE has not been performed as the registered substance is manufactured/imported/marketed at <100 tpa and is not classified as STOT-RE 1 or 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: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol

Related composition: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) - Registration boundary conditions (Solution)

Classification: data conclusive but not sufficient for classification

6.2. Flammability

Flammability

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

Flash Point

The available information on flash point is summarised in the following table:

Table 6.1. Information on flash point

Method	Results	Remarks
Determination of flash point equilibrium method closed cup according to EU Method A.9 (Flash-Point) ; according to ISO 3679 (Determination of flash point - Rapid equilibrium closed cup method)	Flash point: (no flash point - measurement carried out until boiling temperature - No flash point was detected up to the beginning of boiling. The test was stopped at 106°C.) Remarks: The preliminary test with 2 mL test item (starting temperature: 20 °C) showed no ignition up to 100°C. At 100°C the test was stopped. The preliminary test with 4 mL test item (starting temperature: 100°C) showed no ignition up to 106°C. At 106°C (oven temperature) boiling was observed. Afterwards the test was stopped. Due to the ongoing boiling the composition of the test item changes. These changes will become more and more pronounced with increasing temperatures. Additionally, if the temperature of the oven is above the boiling point a major part of the test item will vaporize after being put into the apparatus and hence fill the space above the remaining test item with vapour: in exchange of air no flammable vapour/air mixture is present.	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, (full information in **Annex II**). **Reference** **Nau M 2018**

Due to the results of the preliminary test the main test was not performed.

Table1: Preliminary test

Test item / g	Starting temperature / °C	Temperature / °C	Ignition + / -
2	20	100	-
4	100	106	-

Discussion

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

No ignition was detected up to the beginning of boiling. The test was stopped at 106°C.

Additional information:

Nau (2017) is a GLP-compliant study following EU method A9. It is reliable without restrictions and can be used as the key study for this endpoint. No ignition was detected up to the beginning of boiling. The test was stopped at 106°C.

Classification according to GHS

Name: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol

Related composition: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) - Registration boundary conditions (Solution)

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

6.3. Oxidising potential

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

Classification according to GHS

Name: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol

Related composition: Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) - Registration boundary conditions (Solution)

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

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

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 OECD Guideline 203 (Fish, Acute Toxicity Test) ; according to EU Method C.1 (Acute Toxicity for Fish)	LC50 (96h): 25.78 mg/L element - Pt (nominal) based on: mortality (95 % Confidence Interval: 18.15 - 36.63 mg Pt/L) LC50 (96h): 76.55 mg/L test mat. (nominal) based on: mortality (95 % Confidence Intervals: 53.89 - 108.75 mg test item/L) NOEC (96h): 21 mg/L test mat. (nominal) based on: mortality NOEC (96h): 7.07 mg/L element - Pt (nominal) based on: mortality LOEC (96h): 46 mg/L test mat. (nominal) based on: mortality LOEC (96h): 15.49 mg/L element - Pt (nominal) based on: mortality	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**
Danio rerio (previous name: Brachydanio rerio) freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test) ; according to EU Method C.1 (Acute Toxicity for Fish)	LC50 (96h): >11.1 mg Pt/L element (meas. (arithm. mean)) based on: mortality LC50 (96h): >55.1 mg 2AE/L 2AE (meas. (arithm. mean)) based on: mortality	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol, Form: liquid (full information in **Annex II**). **Reference** **Muth-Kohne E 2016**
Danio rerio (previous name: Brachydanio rerio) freshwater - source water (Cristaline bottled water from Fismes, Marne, France) short-term toxicity to fish according to Afnor: Essai des eaux determination de la toxicite aigue d'une substance vis-a-vis de Brachydanio rerio No 85.202 NFT, pp 90-303	LC50 (96h): 26 mg/L element (dissolved fraction) (meas. (not specified)) based on: mortality	2 (reliable with restrictions) key study experimental study **Test material** Hexachloroplatinic acid; 16941-12-1 / 241-010-7, (full information in

		Annex II). **Reference** **Par R Jouhaud, S Biagianti-Risbourg, F Arsac and G Vernet 1999**

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 OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 0.052 mg/L element - Pt (nominal) based on: mobility (95 % Confidence Interval: 0.044 - 0.064 mg Pt/L) 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 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**
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 20.48 µg/L element - pt (nominal) based on: mobility (95 % Confidence Intervals: 19.06 - 21.99 µg Pt/L) 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 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**
Daphnia magna freshwater semi-static according to OECD Guideline 202	EC50 (48h): 481 µg/L element (meas. (TWA)) based on: mortality (EC50 calculated by extrapolation - 95% Confidence Interval: 374 - 968 µg Pt/L)	1 (reliable without restriction) key study experimental study

(Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 742 µg/L test mat. (meas. (TWA)) based on: mortality (EC50 calculated by extrapolation - 95% Confidence Interval: 577 - 1493 µg test item/L) NOEC (48h): >=572 µg/L test mat. (meas. (TWA)) based on: mortality NOEC (48h): >=371 µg/L element (meas. (TWA)) based on: mortality EC10 (48h): 426 µg/L test mat. (meas. (TWA)) based on: mortality (95% Confidence Interval: 338 - 535 µg test item/L) EC10 (48h): 276 µg/L element - Pt (meas. (TWA)) based on: mortality (95% Confidence Interval: 219 - 347 µg Pt/L)	**Test material** Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid (full information in **Annex II**). **Reference** **Simon M 2014**
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 108 µg/L element (nominal) based on: mortality EC50 (48h): 284 µg/L test mat. (nominal) based on: mortality NOEC (48h): 200 µg/L test mat. (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 semi-static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	NOEC (48h): >=10.9 mg/L element - Pt (meas. (arithm. mean)) based on: mobility EC50 (48h): >902 mg/L test mat. (nominal) based on: mobility EC50 (48h): >54.8 mg/L 2-amino-ethanol (2AE) (meas. (arithm. mean)) based on: mobility EC50 (48h): >10.9 mg/L element - Pt (meas. (arithm. mean)) based on: mobility NOEC (48h): >=902 mg/L test mat. (nominal) based on: mobility NOEC (48h): >=54.8 mg/L 2-amino-ethanol (2AE) (meas. (arithm. mean)) based on: mobility	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol, Form: liquid (full information in **Annex II**). **Reference** **Simon M 2016**
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48h): 140 µg/L element (meas. (not specified)) based on: mobility	2 (reliable with restrictions) key study experimental study

		Test material Hexachloroplatinic acid (hydrate) / 26023-84-7, (full information in **Annex II**). **Reference** **Okamoto A et al 2015**
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48h): 110 µg/L element (meas. (not specified)) based on: immobility LC50 (48h): 157 µg/L element (meas. (not specified)) based on: lethality	2 (reliable with restrictions) key study experimental study **Test material** Hexachloroplatinic acid, Form: Resin (full information in **Annex II**). **Reference** **Zimmermann S et al 2017**

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) key study experimental study **Test material** Hexachloroplatinic acid, (full information in **Annex II**). **Reference** **Biesinger KE, Christensen GM 1972**

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
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]	EC50 (72h): 6.63 mg/L element - Pt (meas. (geom. mean)) based on: growth rate (95% Confidence Interval: 6.25 - 7.08 mg Pt/L) EC10 (72h): 1.98 mg/L element - Pt (meas. (geom. mean)) based on: growth rate (95% Confidence Interval: 1.70 - 2.23 mg Pt/L) EC50 (72h): 3.45 mg/L test mat. (meas. (geom. mean)) based on: yield (95% Confidence Interval: 2.96 - 4.03 mg test item/L) EC50 (72h): 2.24 mg/L element - Pt (meas. (geom. mean)) based on: yield (95% Confidence Interval: 1.92 - 2.61 mg Pt/L) EC50 (72h): 10.2 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95% Confidence Interval: 9.66 - 11.0 mg test item/L) NOEC (72h): 0.946 mg/L test mat. (meas. (geom. mean)) based on: yield NOEC (72h): 0.613 mg/L element - Pt (meas. (geom. mean)) based on: yield NOEC (72h): 1.76 mg/L test mat. (meas. (geom. mean)) based on: growth rate NOEC (72h): 1.14 mg/L element - Pt (meas. (geom. mean)) based on: growth rate EC10 (72h): 1.2 mg/L test mat. (meas. (geom. mean)) based on: yield (95% Confidence Interval: 0.84 - 1.52 mg test item/L) EC10 (72h): 0.778 mg/L element - Pt (meas. (geom. mean)) based on: yield (95% Confidence Interval: 0.546 - 0.989 mg Pt/L) EC10 (72h): 3.06 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95% Confidence Interval: 2.63 - 3.45 mg test item/L)	1 (reliable without restriction) key study experimental study **Test material** Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid: crystalline (full information in **Annex II**). **Reference** **Wenzel A 2014**
Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006] ; according to EU Method C.3 (Algal Inhibition test)	EC50 (72h): 3.3 mg/L element - Pt (nominal) based on: growth rate (95 % Confidence Intervals: 2.41 - 4.63 mg Pt/L) EC10 (72h): 490 µg/L element (dissolved fraction) (nominal) based on: growth rate (EC10 calculated based on reported data and using TRAP 1.30a) 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): 1.32 mg/L element - Pt (nominal) based on: biomass (95 % Confidence Intervals: 0.65 - 2.49 mg Pt/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 NOEC (72h): 0.209 mg/L element - Pt (nominal) based on: biomass NOEC (72h): 1.85 mg/L test mat. (nominal)	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**

	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	
Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006] ; according to EU Method C.3 (Algal Inhibition test)	EC50 (72h): 0.96 mg/L element - platinum (meas. (TWA)) based on: growth rate (95% Confidence Interval: 0.8 - 1.16 mg Pt/L) EC10 (72h): 310 µg/L element (dissolved fraction) (meas. (TWA)) based on: growth rate (EC10 value self-calculated based on reported data using TRAP v1.30a) 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): 0.52 mg/L element - platinum (meas. (TWA)) based on: biomass (95% Confidence Interval: 0.44 - 0.56 mg Pt/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 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**
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]	EC50 (72h): 0.117 mg Pt/L element (meas. (not specified)) based on: growth rate (95%-CL lower = 0.080 mg Pt/L. 95%-CL upper = 0.185 mg Pt/L) EC10 (72h): 0.007 mg Pt/L element (meas. (not specified)) based on: growth rate (95%-CL lower = 0.022 mg Pt/L. 95%-CL upper = 0.013 mg Pt/L) EC50 (72h): 0.021 mg Pt/L element (meas. (not specified)) based on: Yield (95%-CL lower = 0.017 mg Pt/L. 95%-CL upper = 0.026 mg Pt/L.) EC50 (72h): 0.433 mg 2AE/L 2AE (meas. (not specified)) based on: growth rate (95%-CL lower = 0.294 mg 2AE/L. 95%-CL upper = 0.681 mg 2AE/L) EC50 (72h): 0.073 mg 2AE/L 2AE (meas. (not specified)) based on: Yield (95%-CL lower = .0.45 mg 2AE/L. 95% CL-upper = 0.117 mg 2AE/L) EC50 (72h): 0.682 mg/L test mat. (meas. (not specified)) based on: growth rate (95%-CL lower = 0.466 mg/L 95%-CL upper =	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol, (full information in **Annex II**). **Reference** **Wenzel A 2016**

	1.08 mg/L. Test item concentration calculated based on measured Pt concentrations.) EC50 (72h): 0.125 mg/L test mat. (meas. (not specified)) based on: Yield (95%-CL lower = 0.101 mg/L. 95%-CL upper = 0.149 mg/L. Test item concentration calculated based on measured Pt concentrations.) EC10 (72h): 0.09 mg Pt/L element (meas. (not specified)) based on: yield (95%-CL lower = 0.05 mg Pt/L. 95%-CL upper = 0.013 mg Pt/L) EC10 (72h): 0.021 mg 2AE/L 2AE (meas. (not specified)) based on: growth rate (95%-CL lower = 0.006 mg 2AE/L. 95%CL-upper = 0.042 mg 2AE/L) EC10 (72h): 0.032 mg 2AE/L 2AE (meas. (not specified)) based on: Yield (95%-CL lower = 0.022 mg 2AE/L. 95%-CL upper = 0.048 mg 2AE/L) EC10 (72h): 0.039 mg/L test mat. (meas. (not specified)) based on: growth rate (95%-CL lower = 0.012 mg/L. 95%-CL upper = 0.077 mg/L. Test item concentration calculated based on measured Pt concentrations.) EC10 (72h): 0.055 mg/L test mat. (meas. (not specified)) based on: Yield (95%-CL lower = 0.032 mg/L. 95%-CL upper= 0.073 mg/L. Test item concentration calculated based on measured Pt concentrations.)	
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum)	EC50 (48h): 1300 µg/L element (meas. (not specified)) based on: growth (95%CI 1100-1500 µg Pt/L) EC10 (48h): 380 µg/L element (meas. (not specified)) based on: growth (95%CI 270-540 µg Pt/L)	2 (reliable with restrictions) key study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference** **Sorensen S et al 2016**
Chlamydomonas reinhardtii (algae) freshwater toxicity to aquatic algae and cyanobacteria according to ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum)	EC50 (48h): 7100 µg/L element (meas. (not specified)) based on: growth (95%CI 6300-8100 µg Pt/L) EC10 (48h): 1500 µg/L element (meas. (not specified)) based on: growth (95%CI 1100-2000 µg Pt/L) EC50 (48h): 360000 µg/L element (meas. (not specified)) based on: 14C assimilation (95% CI 240000-540000 µg Pt/L) EC10 (48h): 35000 µg/L element (meas. (not specified)) based on: 14C assimilation (95%CI 16000-78000 µg Pt/L)	2 (reliable with restrictions) key study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference**

		Sorensen S et al 2016

7.1.4. Sediment organisms

No relevant information available.

7.1.5. Other aquatic organisms

No relevant information available.

7.2. Terrestrial compartment

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 according to OECD Guideline 220 (Enchytraeid Reproduction Test)	EC10 (28d): 300 mg/kg soil dw element (nominal) based on: reproduction (EC10 value calculated based on reported results using TRAP v1.30a) EC50 (28d): 695 mg/kg soil dw element (nominal) based on: reproduction (EC50 value calculated based on reported results using TRAP v1.30a) 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) supporting study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference** **Havelkova. B et al. 2014**
Folsomia candida [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods: long-term (laboratory study) according to OECD Guideline 232 (Collembolan Reproduction Test in Soil)	NOEC (28d): 5 µmol/L test mat. (nominal) based on: reproduction (- corresponds to 0.19 mg Pt/kg (dry soil)) EC10 - self-calculated from data using log-logistic model by minimising unweighted squared residuals sum (28d): 0.36 mg/kg soil dw element (nominal) based on: reproduction EC10 (28d): 33.6 mg/kg soil dw element (nominal) based on: reproduction (EC10 recalculated based on reported data using TRAP v1.30a) EC50 (28d): 200.4 µmol/L test mat. (nominal) based on: reproduction (corresponding to 7.43 mg Pt/kg(dw)) EC50 (28d): 421 mg/kg soil dw element (nominal) based on: reproduction (EC50 value recalculated based on reported data	2 (reliable with restrictions) supporting study experimental study **Test material** Platinum(IV) chloride, (full information in **Annex II**). **Reference** **Nemcova B et al 2012**

	using TRAP v1.30a)	

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

The results are summarised in the following table:

Table 7.6. Effects on terrestrial arthropods

Method	Results	Remarks

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 7.7. Effects on micro-organisms

Method	Results	Remarks
activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition Test)	EC10 (3h): 648 mg/L element - Pt (nominal) based on: inhibition of total respiration NOEC (3h): 320 mg/L test mat. (nominal) based on: inhibition of total respiration NOEC (3h): 207 mg/L element - Pt (nominal) based on: inhibition of total respiration NOEC (3h): 1000 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration NOEC (3h): 648 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration EC10 (3h): 1000 mg/L test mat. (nominal) based on: inhibition of total respiration EC10 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration EC10 (3h): >648 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration EC50 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of total respiration EC50 (3h): >648 mg/L element - Pt (nominal) based on: inhibition of total respiration	1 (reliable without restriction) key study experimental study **Test material** Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2, Form: solid: crystalline (full information in **Annex II**). **Reference** **Muckle M 2014**

	EC50 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration EC50 (3h): >648 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration	
activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition Test)	EC10 (3h): 2.35 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 2.15 - 2.55 mg/L) 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): 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**
activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition	EC10 (3h): 20.58 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 14.41 - 25.73 mg/L. Without ATU.) NOEC (3h): 60 mg/L test mat. (nominal) based on: inhibition of total respiration (Without ATU.) NOEC (3h): 10.29 mg/L element - Pt (nominal) based on: inhibition of total	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen hexahydroxyplatinate, compound with 2-

Test)	respiration (Without ATU.) NOEC (3h): 130 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (With ATU.) NOEC (3h): 22.3 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (With ATU.) EC10 (3h): 120 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 84- 150 mg/L. Without ATU.) EC10 (3h): 170 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 140 - 210 mg/L. With ATU.) EC10 (3h): 29.16 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: 24.01 - 36.02 mg/L. With ATU.) EC50 (3h): 1100 mg/L test mat. (nominal) based on: inhibition of total respiration (95% Confidence Interval: 850 - 1400 mg/L. Without ATU.) EC50 (3h): 188.65 mg/L element - Pt (nominal) based on: inhibition of total respiration (95% Confidence Interval: 146 - 240.1 mg/L. Without ATU.) EC50 (3h): 1400 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: not determined. With ATU.) EC50 (3h): 240.1 mg/L element - Pt (nominal) based on: inhibition of heterotrophic respiration (95% Confidence Interval: not determined. With ATU.)	amino-ethanol, Form: liquid (full information in **Annex II**). **Reference** **Muckle M 2016**

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 7.8. 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:	PNEC aqua (freshwater) cfr. PNEC derivation report (IUCLID Section 13)
Marine water	PNEC aqua (marine water): 0.014µg/L Intermittent releases:	Assessment factor: 500 Extrapolation method: assessment factor PNEC aqua (marine water) cfr. PNEC derivation report (IUCLID Section 13)
Sediments (freshwater)	PNEC sediment (freshwater): 0.261mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (freshwater) cfr. PNEC derivation report (IUCLID Section 13)
Sediments (marine water)	PNEC sediment (marine water): 0.026mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (marine water) cfr. PNEC derivation report (IUCLID Section 13)
Sewage treatment plant	PNEC STP: 235µg/L	Assessment factor: 10 Extrapolation method: assessment factor PNEC STP cfr. PNEC derivation report (IUCLID Section 13)
Soil	PNEC soil: 0.005mg/kg soil dw	Extrapolation method: equilibrium partitioning method PNEC soil cfr. PNEC derivation report (IUCLID Section 13)
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	no potential for bioaccumulation:	A secondary poisoning assessment is not required for dihydrogen hexahydroxyplatinate and dihydrogen hexahydroxyplatinate,compound with 2-aminoethanol (1:2) as they do not have the potential to cause toxic effects if accumulated in higher organisms, as it is not classified as H360 “May damage fertility or the unborn child”, H361 “Suspected of damaging fertility or the unborn child”, H362 “May cause harm to breastfed children”, H372 “Causes damage to organs through prolonged or repeated exposure” or H373 “May cause damage to organs through prolonged or repeated exposure”.

		For exachloroplatinic acid, diammonium hexachloroplatinate and dipotassium hexachloroplatinate, no or insufficient data are available at present, but exposure to chloroplatinates in the environment is expected to be very limited.

Conclusion on environmental classification

Environmental classification for the platinum(IV) substances under consideration is based on the lowest acute and chronic threshold values from the Pt(IV) ecotoxicity test data:

-acute ERV: lowest acute threshold value is 99 µg Pt/L (geometric mean EC50 value with D. magna, based on the experimental results for hexachloroplatinic acid (n=3), dihydrogen hexahydroxoplatinate and diammonium hexachloroplatinate)

-chronic ERV: lowest chronic threshold value is 7 µg Pt/L (NOEC value (calculated as EC16/2) with D. magna, based on the experimental results for hexachloroplatinic acid.

The derivation of both ERV values is detailed in the read-across justification report (cfr. IUCLID Section 13) and PNEC derivation report (cfr. IUCLID Section 13).

For classification purposes, these ERVs have been recalculated to the values expressed as the concentration of the substance (conversion based on molecular weight conversion from soluble ion to the substance considered – cfr. details in below table). This results in a classification as Acute Category 1 and Chronic Category 1 for all substances contained in the below table. Acute and chronic M-factors are based on the value of the substance-specific acute and chronic ERV, as outlined in ECHA Guidance on the application of the CLP criteria (version 5.0; ECHA, 2017) - cfr. below table.

However, and as explained in the read-across justification document attached in IUCLID section 13, for platinum (IV) substances, there is some uncertainty related to potential observed (and currently unexplained) differences in effects thresholds observed between chloride and hydroxide coordinated Pt(IV) substances. As will be shown, under ecologically relevant conditions, they will all respeciate to a similar [Pt(OH)2]0species. However, the kinetics of this process are currently unknown.

Therefore, the approach for hazard assessment and classification considers these potential/temporal differences in toxicity due to the co-ordinating ligands: the classification is derived based on the substance specific test data and based on the test data for the category as described below. **The most conservative classification will be applied.**

				Classification using category data	Classification using substance specific data						
	Molecular formula	MW	Pt (wt%)	Acute ERV (µg TI/L)	Chronic ERV (µg TI/L)	Aq Acute classif	Aq Chron classif	Acute ERV (µg TI/L)	Chronic ERV (µg TI/L)	Aq Acute classif	Aq Chron classif
Diammonium hexachloroplatinate	(NH4)2[PtCl6]	443.87	43.9	221.7	15.9	Aq Acute 1, M=1	Aq Chron 1, M=1	284 (Simon,2014)$	17 (Biesinger&Christensen,1972)$	Aq Acute 1, M=1	Aq Chron 1, M=1

Dipotassium hexachloroplatinate	K2[PtCl6]	485.98	40.1	242.7	17.4	Aq Acute 1, M=1	Aq Chron 1, M=1	51 (Moll& Wydra, 2005)£	17 (Biesinger&Christensen, 1972)£	Aq Acute 1, M=10	Aq Chron 1, M=10
Hexachloroplatinic acid	H2[PtCl6]	409.8	47.6	204.7	14.7	Aq Acute 1, M=1	Aq Chron 1, M=1	60.8 (Moll& Wydra, 2005)*	14 (Biesinger&Christensen, 1972)*	Aq Acute 1, M=10	Aq Chron 1, M=10
Dihydrogen hexahydroxyplatinate	H2[PtOH6]	299.14	65.2	149.4	10.7	Aq Acute 1, M=1	Aq Chron 1, M=1	742 (Simon, 2014)+	946 (Wenzel, 2014)+	Aq Acute 1, M=1	Aq Chron 1, M=1
Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2)	(HO-C2H4-NH3)2Pt(OH)6	421.3	46.3	210.4	15.1	Aq Acute 1, M=1	Aq Chron 1, M=1	682 (Wenzel, 2016)%	39 (Wenzel, 2016)%	Aq Acute 1, M=1	Aq Chron 1, M=1

* Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests performed with the substance itself. For this substance, the lowest acute value is a 48-hour EC50 of 0.0608 mg test item L-1 (0.0205 mg Pt L-1) for aquatic invertebrates(mobility) and the lowest chronic value is a 21-day NOEC value of 0.007 mg Pt L-1 (0.014 mg test item L-1) for Daphnia, based on reproduction. A full chronic dataset (fish, Daphnia and algae) is not available for this substance, therefore classification has been assessed based on both the acute and chronic data, with the worst case classification assigned. An environmental classification of Acute Category 1, Chronic Category 1 is assigned to this substance, based on the acute data. As the lowest EC50 value is >0.01 ≤ 0.1 an acute M factor of 10 is assigned. A chronic M factor of 10 is also assigned, to match the acute M factor, as the classification has been determined based on acute data.

$ 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 ≤ 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.

£ Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests. For this substance, all values are read across from hexachloroplatinic acid. For classification purposes, these values have been expressed as concentrations of dipotassium hexachloroplatinate, converted based on molecular weight. The lowest acute value is a 48-hour EC50 of 0.0205 mg Pt L-1for aquatic invertebrates(mobility) and the lowest chronic value is a 21-day NOEC value of 0.007 mg Pt L-1 for Daphnia, based on reproduction. This results in an EC50 of 0.051 mg dipotassium hexachloroplatinate L-1 and a NOEC of 0.017 mg dipotassium hexachloroplatinate L- 1. A full chronic dataset (fish, Daphnia and algae) is not available for this substance,

therefore classification has been assessed based on both the acute and chronic data, with the worst case classification assigned. An environmental classification of Acute Category 1, Chronic Category 1 is assigned to this substance, based on acute data. As the lowest EC50 value is >0.01 ? 0.1 an acute M factor of 10 is assigned. A chronic M factor of 10 is also assigned, to match the acute M factor, as the classification has been determined based on acute data

+ Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests performed with the substance itself. The lowest acute value is a 48 -hour EC50 of 0.742 mg test item L-1 (0.481 mg Pt L-1) for aquatic invertebrates(mobility) and the lowest chronic value is a 72-hour NOEC of 0.946 mg test item L-1 (0.613 mg Pt L-1) for algae (yield and growth rate). For this substance, the only chronic data available is an algal NOEC, therefore classification is assessed based on both the acute and chronic data and the worst case classification assigned to the substance. Based on these results, an environmental classification of Acute Category 1, Chronic Category 1 is assigned. As the lowest EC50 value is >0.1 ≤ 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.

% Environmental classification is assessed based on the lowest acute and chronic values from ecotoxicity tests. A full base set of ecotoxicity data are available for this substance, and both platinum and 2-aminoethanol concentrations were analysed in the studies. For fish and Daphnia, no effects were observed up to the highest test concentration. Classification of this substance is therefore based on the algal results and test item concentrations in the study were determined based on measured platinum concentrations. The lowest acute value is a 48-hour EC50 of 0.682 mg test item L-1 (growth rate) and the lowest chronic value is a 72-hour EC10 of 0.039 mg test item L-1 (growth rate). For this substance, the only chronic data available is an algal EC10, therefore classification is assessed based on both the acute and chronic data and the worst case classification assigned to the substance. Based on these results, an environmental classification of Acute Category 1, Chronic Category 1 is assigned to this substance. As the lowest EC50 value is >0.1 ≤ 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.

General discussion

This substance is a member of the category of “Platinum(IV) substances“. As such,

the data requirements for this substance are covered by relevant and reliable experimental test data generated for all members of this category via a read-across approach.

A read-across justification report and PNEC derivation report are attached in IUCLID Annex 13.

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. PBT/vPvB criteria and justification

8.1.1.1. Assessed substance: (group of) constituent(s) /impurities/additives

PBT status of the assessed substance: the substance is not PBT / vPvB
Remark for assessed substance: PBT assessment is not relevant for inorganic substances. However, as this substance has an organic component a PBT assessment has been conducted for the organic part of the substance.

8.1.1.1.1. Persistence assessment

Evidence of non-P / non-vP properties

Screening criteria
- Not P / vP based on ready biodegradability: The organic component of this substance, 2-aminoethanol, is readily biodegradable based on ready biodegradation studies conducted following modified OECD and modified sturm test methods. The pass criterion of >70% degradation was met (Kuenemann 1992). As the organic component of the substance is readily biodegradable, the substance is not considered to be persistent.

Conclusion on P / vP properties:

not P/vP.

8.1.1.1.2. Bioaccumulation assessment

Evidence of non-B / non-vB properties

Screening criteria
- Remarks on criterion “Log Kow<=4.5”: The organic component of this substance has a log Kow of -1.31 (Hansch et al. 1995), which is below the threshold for bioaccumulation of 4.5. As the organic component of the substance has a log Kow <4.5, the substance is not considered to be bioaccumulative.

Conclusion on B / vB properties:

not B/vB.

8.1.1.1.3. Toxicity assessment

Evidence of non-T properties

Criteria based on Annex XIII of REACH
- Not T based on criteria laid down in Annex XIII of REACH:
    - EC10 / NOEC>=0.01 mg/L for marine / freshwater organisms (long-term toxicity): Acute ecotoxicity data are available for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol for fish, Daphnia and algae. The most sensitive trophic level was algae, with an EC50 of 0.682 mg test item L-1, an EC10 of 0.039 mg test item L-1 and a NOEC of 0.092 mg test item L-1. As the EC50, EC10 and NOEC values are above 0.01 mg L-1, the substance is not considered to be Toxic. Substance is not classified as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) according to Regulation EC No 1272/2008 (or CLP Regulation) (see also section “3. Classification and labelling”): This substance is not classed as mutagenic (category 1A or 1B), carcinogenic (category 1A or 1B), or toxic to reproduction (category 1A, 1B or 2) according to EU CLP criteria. Therefore, it does not fulfil the criteria for toxicity (T).
    - No other evidence of chronic toxicity, as identified by or specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008: This substance is not classed as STOT RE (category 1 or 2) according to EU CLP criteria. Therefore, it does not fulfil the

criteria for toxicity (T).

Conclusion on T properties:

not T.

8.1.2. Summary and overall conclusions on PBT or vPvB properties

Assessment entity linked:
dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol. View the assessment entity table in chapter 1.3 **here**;
Pt dissolved. View the assessment entity table in chapter 1.3 **here**

Overall conclusion: Based on the assessment described in the subsections above the submission substance is not a PBT / vPvB substance.

Justification:

PBT assessment is not relevant for inorganic substances. However, as this substance has an organic component a PBT assessment has been conducted for the organic part of the substance. Based on data for 2-aminoethanol it is not considered to be PBT, as it is readily biodegradable and has a log Kow of -1.31. 2-aminoethanol, the organic component of this substance, is therefore not persistent or bioaccumulative and therefore not PBT or vPvB.

8.2. Emission characterisation

9. EXPOSURE ASSESSMENT (and related risk characterisation)

The sections 9 and 10 of this CSR have been generated with Chesar 3.5.

9.0. Introduction

9.0.1. Overview on uses

See the description of the various uses in section 2 of the CSR.

9.0.2. Assessment entity groups

As described in section 1 of the CSR several sets of substance properties are needed for the human health and environmental assessment. Therefore assessment entities (AEs) have been defined (see section 1.3), for which relevant properties have been reported in section 1 to 7.
Each contributing scenario has been assessed using the properties of one or more assessment entities, grouped into "assessment entity groups". The defined assessment entity groups are reported in the following table.

Table 9.1. Assessment entity groups

Assessment entity group (AEG) name	Composition of AEG	Remarks
Pt dissolved for ENV RA	• 100% Pt dissolved	**Relevant for the assessment of contributing scenarios for:** - Environment and Man via environment **Method for calculating the RCR across the AEs:** Summed RCR
HHPA-2AE for OCC	• 100% dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	**Relevant for the assessment of contributing scenarios for:** - Workers/Consumers **Method for calculating the RCR across the AEs:** Summed RCR

9.0.3. Introduction to the assessment for the environment

9.0.3.1. Tonnage

Assessed tonnage: 30 tonnes/year based on:

- 30 tonnes/year manufactured

The following table provides the tonnage per use and the local tonnages used in the assessment for each environmental contributing activity. The local tonnage corresponds to a tonnage at the site for uses taking place at industrial sites and to a tonnage assumed for a town of 10 000 inhabitants for widespread uses.

Table 9.2. Tonnage for assessment

ES#	Exposure scenario (ES) name and related environmental contributing scenarios	Tonnage per use (t/year)	Daily local tonnage (t/day)	Annual local tonnage (t/year)
ES1 (M)	Manufacture of the substance (as such)	30		
	- Manufacture of the substance (as such) ES 1.1 (ERC 1)		0.091	30
	- Manufacture of the substance (as such) ES 1.2 (ERC 1)		0.091	30
ES2 (IS)	Use as an intermediate	30		
	- Use as an intermediate ES 2.1 (ERC 6a)		0.091	30
	- Use as an intermediate ES 2.2 (ERC 6a)		0.091	30

9.0.3.2. Scope and type of assessment for the environment

The scope of exposure assessment and type of risk characterisation required for the environment are described in the following table based on the hazard conclusions presented in section 7.

Table 9.3. Type of risk characterisation required for the environment

Protection target	Assessment entity	Risk characterisation type	Hazard conclusion (see section 7)
Fresh water	Pt dissolved	Quantitative	PNEC aqua (freshwater) = 0.14 µg/L
Sediment (freshwater)	Pt dissolved	Quantitative	PNEC sediment (freshwater) = 0.261 mg/kg sediment dw
Marine water	Pt dissolved	Quantitative	PNEC aqua (marine water) = 0.014 µg/L
Sediment (marine water)	Pt dissolved	Quantitative	PNEC sediment (marine water) = 0.026 mg/kg sediment dw
Sewage Treatment Plant	Pt dissolved	Quantitative	PNEC STP = 235 µg/L
Air	Pt dissolved	Not needed	No hazard identified
Agricultural soil	Pt dissolved	Quantitative	PNEC soil = 5.23E-3 mg/kg soil dw
Predator’s prey (freshwater)	Pt dissolved	Not needed	No potential for bioaccumulation
Predator’s prey (marine water)	Pt dissolved	Not needed	No potential for bioaccumulation
Top predator’s prey (marine water)	Pt dissolved	Not needed	No potential for bioaccumulation
Predator’s prey (terrestrial)	Pt dissolved	Not needed	No potential for bioaccumulation

9.0.3.3. Fate and distribution parameters

Physicochemical properties used for exposure estimation

The following substance properties are used in the fate estimation done by EUSES. They correspond to the “value used for CSA” reported in sections 1 and 4.

Table 9.4. Substance key phys-chem and fate properties

Substance property	Pt dissolved
Molecular weight	≥ 195.0
Molecular weight used for the assessment	195.0
Melting point at 101 325 Pa	-8 °C
Vapour pressure	23.9 hPa at 20 °C
Water solubility	1 g/L at 20 °C
Log Kp (solids-water in soil)	1.57
Log Kp (solids water in sediment)	3.27
Log Kp (solids-water in suspended matter)	3.27
Log Kp (solids-	3.27

Substance property	Pt dissolved
water in raw sewage sludge)	
Log Kp (solids-water in settled sewage sludge)	3.27
Log Kp (solids-water in activated sewage sludge)	3.27
Log Kp (solids-water in effluent sewage sludge)	3.27

Fate (release percentage) in the modelled biological sewage treatment plant

In a standard (modelled) biological STP, the emissions are distributed in the following way:

Assessment entities	Pt dissolved
Release to water	42.9%
Release to air	0%
Release to sludge	57.1%
Release degraded	0%

The above fractions are calculated by the SIMPLETREAT model integrated in EUSES for the following assessment entities: dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol.
The fractions reported in the above table have been set by the assessor for some assessment entities.
Explanation for Pt dissolved:
Based on European STP monitoring programme. 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

9.0.3.4. Comments on assessment approach for the environment

The regional concentrations are reported in section 10.2.1.1. The local Predicted Exposure Concentrations (PECs) reported for each contributing scenario correspond to the sum of the local concentrations (Clocal) and the regional concentrations (PEC regional).
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.
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 platinum substances 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, 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 based on data from 10 sites) 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 four 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 to water and air based on RFs taken from the SpERC documents have been adjusted to 10% of the recommended value.

Summary information gathered from the Pt industry:

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)	

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	2253.2	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 & 2.2 Freshwater – direct discharge to water		3000		1000 max (dilution factor for only site with direct discharge is 4800)		

9.0.3.5. Scope and type of assessment for man via environment

The exposure assessment for man via environment is not needed.
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 (2016) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 3.0, February 2016))

9.0.4. Introduction to the assessment for workers

9.0.4.1. Scope and type of assessment for workers

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.

Table 9.5. Type of risk characterisation required for workers

Route	Type of effect	Assessment entity	Risk characterisation type	Hazard conclusion (see section 5.11)
Inhalation	Systemic effects - long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Quantitative	DNEL (Derived No Effect Level) = 0.023 mg/m³
	Systemic effects - acute	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Not needed	No hazard identified
	Local effects - long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Qualitative	Medium hazard (no threshold derived)
Dermal	Systemic effects - long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Quantitative	DNEL (Derived No Effect Level) = 0.016 mg/kg bw/day
	Systemic effects - acute	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Not needed	No hazard identified
	Local effects - long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Qualitative	Medium hazard (no threshold derived)
Eye	Local effects	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	Qualitative	Medium hazard (no threshold derived)

9.0.4.2. Comments on assessment approach for workers

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) contaminated 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).
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 not part of this assessment are handled in dedicated areas.
ORGANISATIONAL MEASURES - All machinery/systems and risk management measure are regulary 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.

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.

9.0.5. Introduction to the assessment for consumers

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

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

Environment contributing scenario(s):		
CS 1	Manufacture of the substance (as such) ES 1.1	ERC 1
CS 2	Manufacture of the substance (as such) ES 1.2	ERC 1
Worker contributing scenario(s):		
CS 3	Raw material handling of dry/dusty materials	PROC 26
CS 4	Raw material handling of non to low dusty platinum substances	PROC 21
CS 5	Raw material handling of liquid platinum substances	PROC 8b, PROC 9
CS 6	Raw material handling of platinum substances in fully contained systems	PROC 1
CS 7	Sampling/Evaluation of solid platinum substances	PROC 15
CS 8	Sampling/Evaluation of liquid platinum substances	PROC 15
CS 9	Wet processing in fully contained systems	PROC 1
CS 10	Wet processing in not fully contained systems	PROC 2, PROC 3; PROC 4; PROC 5
CS 11	Packaging/Filling of liquid platinum substances	PROC 8b, PROC 9
CS 12	Packaging/Filling in fully contained systems	PROC 1
CS 13	Cleaning and maintenance: vacuum cleaning	PROC 26
CS 14	Cleaning and maintenance: wet cleaning	PROC 8a

Further description of the use:

The insoluble substance Dihydrogen hexahydroxyplatinate is dissolved in a mixture of water and 2-aminoethanol. During the solution step the substance Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) is formed. The solution may be used for further processing and production of platinum compounds.

9.1.1. Env CS 1: Manufacture of the substance (as such) ES 1.1 (ERC 1)

Assessment entity group used for the assessment of this contributing scenario: Pt dissolved for ENV RA

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 30 tonnes/year *64.8 tonnes dihydrogen hexahydroxyplatinate with 2-aminoethanol (1:2) (30 tonnes Pt metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.091 tonnes/day *Based on 330 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 57.1%]
• Discharge rate of STP: >= 3E3 m3/day
• Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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)*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 9.3E4 m3/day
• Discharge to: Freshwater only

Fate (release percentage) in the biological sewage treatment plant

The biological STP is site specific and the releases to the various compartments have been set by the assessor for some assessment entities. They are distributed in the following way:

Assessment entities	**Pt dissolved**
Release to water	42.9%
Release to air	0%
Release to sludge	57.1%
Release degraded	0%

Explanation for Pt dissolved:
Based on European STP monitoring programme. 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

9.1.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.6. Local releases to the environment

Release	**Assessment entity**	**Release estimation method**	**Explanations**
Water	Pt dissolved	Estimated release factor	**Release factor before on site RMM:** 1.19E-3% **Release factor after on site RMM:** 1.19E-3% **Local release rate:** 1.08E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99 % (sector data) Release factor after on-site treatment: 11.9 g/T (50P from sector data)
Air	Pt dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.73E-3 kg/day **Explanation:** 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')
Non agricultural soil	Pt dissolved	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** No direct emissions to soil.

9.1.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.7. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pt dissolved	**Local PEC:** 4.74E-6 mg/L RCR = 0.034	Final RCR = 0.034
Sediment (freshwater)	Pt dissolved	**Local PEC:** 8.84E-3 mg/kg dw RCR = 0.034	Final RCR = 0.034
Sewage Treatment Plant	Pt dissolved	**Local PEC:** 1.55E-4 mg/L RCR = 6.59E-4	Final RCR < 0.01
Agricultural soil	Pt dissolved	**Local PEC:** 9.53E-4 mg/kg dw RCR = 0.182	Final RCR = 0.182

9.1.2. Env CS 2: Manufacture of the substance (as such) ES 1.2 (ERC 1)

Assessment entity group used for the assessment of this contributing scenario: Pt dissolved for ENV RA

9.1.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 30 tonnes/year *64.8 tonnes dihydrogen hexahydroxyplatinate with 2-aminoethanol (1:2) (30 tonnes Pt metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.091 tonnes/day *Based on 330 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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)*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 3E6 m3/day
• Discharge to: Freshwater only
• Discharge rate of effluent: >= 3E3 m3/day

9.1.2.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.8. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pt dissolved	Estimated release factor	**Release factor before on site RMM:** 1.19E-3% **Release factor after on site RMM:** 1.19E-3% **Local release rate:** 1.08E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99 % (sector data) Release factor after on-site treatment: 11.9 g/T (50P from sector data)
Air	Pt dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.73E-3 kg/day **Explanation:** 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')
Non agricultural soil	Pt dissolved	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** No direct emissions to soil.

9.1.2.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.9. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pt dissolved	**Local PEC:** 3.83E-7 mg/L RCR = 2.74E-3	Final RCR < 0.01
Sediment (freshwater)	Pt dissolved	**Local PEC:** 7.14E-4 mg/kg dw RCR = 2.74E-3	Final RCR < 0.01
Agricultural soil	Pt dissolved	**Local PEC:** 9.53E-4 mg/kg dw RCR = 0.182	Final RCR = 0.182

9.1.3. Worker CS 3: Raw material handling of dry/dusty materials (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.3.1. Conditions of use

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

	Method
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: - *Generic local exhaust ventilation* - *Exterior exhaust ventilation* - *Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances 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: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty 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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.1.3.2. Exposure and risks for workers

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

Table 9.10. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	3.63 µg/m³ (Measured data: Analogous data) RCR = 0.158	Final RCR = 0.158
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:

Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 3.7
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #1 (GSD=3.7) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of the use of appropriate gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.4. Worker CS 4: Raw material handling of non to low dusty platinum substances (PROC 21)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: Low *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Exterior exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Containment due to physical form *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: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Dusty 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*	

	Method
information on how clean work environments are ensured and on how to contamination is avoided in the platinum industry.	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.1.4.2. Exposure and risks for workers

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

Table 9.11. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.38 µg/m³ (Measured data: Analogous data) RCR = 0.017	Final RCR = 0.017
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.5. Worker CS 5: Raw material handling of liquid platinum substances (PROC 8b, PROC 9)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances 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: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.1.5.2. Exposure and risks for workers

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

Table 9.12. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.38 µg/m³ (Measured data: Analogous data) RCR = 0.017	Final RCR = 0.017
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9
Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 7
Explanation: The estimated exposure level (< 1µg/cm2) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.6. Worker CS 6: Raw material handling of platinum substances in fully contained systems (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.6.1. Conditions of use

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

	Method
Technical and organisational conditions and measures	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• 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: 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. [Effectiveness Dermal: 90%] *Precautionary measure as gloves are not needed to demonstrate safe use.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.1.6.2. Exposure and risks for workers

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

Table 9.13. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.01 µg/m³ (Measured data: Pt monitoring database) RCR = 4.35E-4	Final RCR < 0.01
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 12
Explanation: The estimated exposure level (< 1µg/cm2) represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.7. Worker CS 7: Sampling/Evaluation of solid platinum substances (PROC 15)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *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: As high as possible to reduce potential for exposure. Although automation may not be possible during this task, an incidental or intermittent contact level is achieved by limiting the number of exposure events (see the dermal exposure pattern below).	
• Removal of residuals: Dusty 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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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*	

	Method
contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

9.1.7.2. Exposure and risks for workers

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

Table 9.14. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	3.25 µg/m³ (Measured data: Analogous data) RCR = 0.141	Final RCR = 0.141
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 14 ; GSD: 4.3
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #05 (GSD=4.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.8. Worker CS 8: Sampling/Evaluation of liquid platinum substances (PROC 15)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	

	Method
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Containment due to physical form *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: As high as possible to reduce potential for exposure. Although automation may not be possible during this task, an incidental or intermittent contact level is achieved by limiting the number of exposure events (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.1.8.2. Exposure and risks for workers

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

Table 9.15. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.08 µg/m³ (Measured data: Analogous data) RCR = 3.48E-3	Final RCR < 0.01
Dermal, local, long term	dihydrogen hexahydroxyplatinat	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
	e, compound with 2-aminoethanol		
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value multiplied with 1.5 of the exposure distribution for estimate #06 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 26
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.9. Worker CS 9: Wet processing in fully contained systems (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.9.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	

	Method
• Dermal contact level: None	
• 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: 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. [Effectiveness Dermal: 90%] *Precautionary measure as gloves are not needed to demonstrate safe use.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.1.9.2. Exposure and risks for workers

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

Table 9.16. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.01 µg/m³ (Measured data: Pt monitoring database) RCR = 4.35E-4	Final RCR < 0.01
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	2 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.10. Worker CS 10: Wet processing in not fully contained systems (PROC 2, PROC 3; PROC 4; PROC 5)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.10.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances 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: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: Yes (Respirator with APF of 10) [Effectiveness Inhalation: 90%]	

9.1.10.2. Exposure and risks for workers

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

Table 9.17. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	5.613 µg/m³ (Measured data: Pt monitoring database) RCR = 0.244	Final RCR = 0.244
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: sol Pt
Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 16.7
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #10 (GSD=16.7) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document in combination with RPE (APF = 10).

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 7
Explanation: The estimated exposure level (< 1µg/cm2) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.11. Worker CS 11: Packaging/Filling of liquid platinum substances (PROC 8b, PROC 9)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.11.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low *It is noted that spraying operations are not covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	

	Method
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems *Platinum substances 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: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.1.11.2. Exposure and risks for workers

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

Table 9.18. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.38 µg/m³ (Measured data: Analogous data) RCR = 0.017	Final RCR = 0.017
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: ClPt, sol Pt
Inhalation exposure, long term concentration: Number of measured data points: 3 ; GSD: 1.9

Explanation: The estimated exposure level represents the 95th percentile of the exposure distribution for estimate #02 (GSD=1.9) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 7
Explanation: The estimated exposure level (< 1µg/cm2) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.12. Worker CS 12: Packaging/Filling in fully contained systems (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.12.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• 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: 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. [Effectiveness Dermal: 90%] *Precautionary measure as gloves are not needed to demonstrate safe use.*	

	Method
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.1.12.2. Exposure and risks for workers

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

Table 9.19. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.01 µg/m³ (Measured data: Pt monitoring database) RCR = 4.35E-4	Final RCR < 0.01
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	2 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Pt monitoring database for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: All
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the “Methodology applied in the Occupational Exposure Scenarios for Platinum Substances” document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.13. Worker CS 13: Cleaning and maintenance: vacuum cleaning (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.13.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid *Dusty residuals*	
• Maximum emission potential of the substance: High *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Removal of residuals: 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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.1.13.2. Exposure and risks for workers

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

Table 9.20. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	2.96 µg/m³ (Measured data: Analogous data) RCR = 0.129	Final RCR = 0.129
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: ClPt
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 7
Explanation: The estimated exposure level (<1 µg/cm2) represents the 90th percentile of the exposure distribution for NNE in consideration of the use of appropriate gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.1.14. Worker CS 14: Cleaning and maintenance: wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.1.14.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Removal of residuals: Splashes *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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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*	

	Method
be worn.	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	

9.1.14.2. Exposure and risks for workers

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

Table 9.21. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.03 µg/m³ (Measured data: Analogous data) RCR = 1.3E-3	Final RCR < 0.01
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	10 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: sol Pt
Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 2.2
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #25 (GSD=2.2) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 17
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDE in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.2. Exposure scenario 2: Use at industrial sites - Use as an intermediate

Sector of use: SU 9: Manufacture of fine chemicals; SU 14: Manufacture of basic metals, including alloys

Environment contributing scenario(s):		
CS 1	Use as an intermediate ES 2.1	ERC 6a
CS 2	Use as an intermediate ES 2.2	ERC 6a
Worker contributing scenario(s):		
CS 3	Handling of solutions or low dusty material and reaction	PROC 3, PROC 15; PROC 26; PROC 4; PROC 5; PROC 8b; PROC 9
CS 4	Fully contained process	PROC 1
CS 5	Wet cleaning	PROC 8a
CS 6	Vacuum cleaning	PROC 26

9.2.1. Env CS 1: Use as an intermediate ES 2.1 (ERC 6a)

Assessment entity group used for the assessment of this contributing scenario: Pt dissolved for ENV RA

9.2.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 30 tonnes/year *64.8 tonnes dihydrogen hexahydroxyplatinate with 2-aminoethanol (1:2) (30 tonnes Pt metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.091 tonnes/day *Based on 330 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 57.1%]
• Discharge rate of STP: >= 3E3 m3/day
• Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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)*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 9.3E4 m3/day
• Discharge to: Freshwater only

Fate (release percentage) in the biological sewage treatment plant

The biological STP is site specific and the releases to the various compartments have been set by the assessor

for some assessment entities. They are distributed in the following way:

Assessment entities	Pt dissolved
Release to water	42.9%
Release to air	0%
Release to sludge	57.1%
Release degraded	0%

Explanation for Pt dissolved:
Based on European STP monitoring programme. 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

9.2.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.22. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pt dissolved	Estimated release factor	**Release factor before on site RMM:** 1.19E-3% **Release factor after on site RMM:** 1.19E-3% **Local release rate:** 1.08E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99 % (sector data) Release factor after on-site treatment: 11.9 g/T (50P from sector data)
Air	Pt dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.73E-3 kg/day **Explanation:** 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')
Non agricultural soil	Pt dissolved	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** No direct emissions to soil.

9.2.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.23. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pt dissolved	**Local PEC:** 4.74E-6 mg/L RCR = 0.034	Final RCR = 0.034
Sediment (freshwater)	Pt dissolved	**Local PEC:** 8.84E-3 mg/kg dw RCR = 0.034	Final RCR = 0.034
Sewage Treatment Plant	Pt dissolved	**Local PEC:** 1.55E-4 mg/L RCR = 6.59E-4	Final RCR < 0.01

Protection target	Assessment entity	Exposure concentration	Risk quantification
Agricultural soil	Pt dissolved	**Local PEC:** 9.53E-4 mg/kg dw RCR = 0.182	Final RCR = 0.182

9.2.2. Env CS 2: Use as an intermediate ES 2.2 (ERC 6a)

Assessment entity group used for the assessment of this contributing scenario: Pt dissolved for ENV RA

9.2.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 30 tonnes/year *64.8 tonnes dihydrogen hexahydroxyplatinate with 2-aminoethanol (1:2) (30 tonnes Pt metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.091 tonnes/day *Based on 330 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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)*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 3E6 m3/day
• Discharge to: Freshwater only
• Discharge rate of effluent: >= 3E3 m3/day

9.2.2.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.24. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pt dissolved	Estimated release factor	**Release factor before on site RMM:** 1.19E-3% **Release factor after on site RMM:** 1.19E-3% **Local release rate:** 1.08E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99 % (sector data) Release factor after on-site treatment: 11.9 g/T (50P from sector data)
Air	Pt dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3%

Release	Assessment entity	Release estimation method	Explanations
			Local release rate: 2.73E-3 kg/day **Explanation:** 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')
Non agricultural soil	Pt dissolved	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** No direct emissions to soil.

9.2.2.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.25. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pt dissolved	**Local PEC:** 3.83E-7 mg/L RCR = 2.73E-3	Final RCR < 0.01
Sediment (freshwater)	Pt dissolved	**Local PEC:** 7.14E-4 mg/kg dw RCR = 2.73E-3	Final RCR < 0.01
Agricultural soil	Pt dissolved	**Local PEC:** 9.53E-4 mg/kg dw RCR = 0.182	Final RCR = 0.182

9.2.3. Worker CS 3: Handling of solutions or low dusty material and reaction (PROC 3, PROC 15; PROC 26; PROC 4; PROC 5; PROC 8b; PROC 9)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.2.3.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Various *liquid (solution, suspension) or low dusty solids (e.g. wetted)*	
• Maximum emission potential of the substance: Low *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• The following type of exhaust ventilation are appropriate for handling of platinum substances: *- Generic local exhaust ventilation* *- Integrated exhaust ventilation* *A minimum efficiency of 80 % has to be assured.*	
• Level of containment: Partly contained systems	

	Method
Platinum substances 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: As high as possible to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (see the dermal exposure pattern below).	
• Removal of residuals: Splashes *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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.2.3.2. Exposure and risks for workers

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

Table 9.26. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	5.613 µg/m³ (Measured data: Analogous data) RCR = 0.244	Final RCR = 0.244
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: sol Pt manufacturers wet processing
Inhalation exposure, long term concentration: Number of measured data points: 4 ; GSD: 16.7
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for estimate #10 (GSD=16.7) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document in combination with RPE (APF = 10).

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 7

Explanation: The estimated exposure level (< 1µg/cm2) represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.2.4. Worker CS 4: Fully contained process (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.2.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Unknown *Not relevant (fully contained systems)*	
• Maximum emission potential of the substance: Unknown *Not relevant (fully contained systems)*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Level of containment: Full containment	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
• 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: 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. [Effectiveness Dermal: 90%] *Precautionary measure as gloves are not needed to demonstrate safe use.*	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.2.4.2. Exposure and risks for workers

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

Table 9.27. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.01 µg/m³ (Measured data: Analogous data) RCR = 4.35E-4	Final RCR < 0.01
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	2 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: ClPt manufacturers separation/filtration
Inhalation exposure, long term concentration: Number of measured data points: 8 ; GSD: 2.3
Explanation: The estimated exposure level represents the 95th percentile value of the exposure distribution for the static estimate #14 (GSD=2.3) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 12
Explanation: The estimated exposure level represents 1/10 of the 90th percentile of the exposure distribution for NNI (without gloves).

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.2.5. Worker CS 5: Wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.2.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Liquid *Solution, suspension*	
• Maximum emission potential of the substance: Very low	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Removal of residuals: Splashes *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*	

	Method
to contamination is avoided in the platinum industry. *Workplaces are to be cleaned before any maintenance work starts.*	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.2.5.2. Exposure and risks for workers

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

Table 9.28. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	0.03 µg/m³ (Measured data: Analogous data) RCR = 1.3E-3	Final RCR < 0.01
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	10 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: sol Pt manufacturers Packaging/Filling
Inhalation exposure, long term concentration: Number of measured data points: 2 ; GSD: 2.2
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #25 (GSD=2.2) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 17
Explanation: The estimated exposure level represents the 90th percentile of the exposure distribution for NDE in consideration of appropriate use of gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

9.2.6. Worker CS 6: Vacuum cleaning (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: HHPA-2AE for OCC

9.2.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid *Dusty residuals*	
• Maximum emission potential of the substance: High *Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.*	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Removal of residuals: 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 pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
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. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 protection: No [Effectiveness Inhalation: 0%]	

9.2.6.2. Exposure and risks for workers

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

Table 9.29. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Assessment entity**	**Exposure concentration**	**Risk quantification**
Inhalation, systemic, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	2.96 µg/m³ (Measured data: Analogous data) RCR = 0.129	Final RCR = 0.129

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Dermal, local, long term	dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol	1 µg/cm² (Measured data: Analogous data (Ni))	Risk adequately controlled
Combined routes, systemic, long-term			Risk adequately controlled

Remarks on measured exposure:

Analogous data for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: ClPt manufacturers cleaning and maintenance
Inhalation exposure, long term concentration: Number of measured data points: 17 ; GSD: 5.1
Explanation: The estimated exposure level represents the maximum value of the exposure distribution for estimate #27 (GSD=5.1) taken from the Pt monitoring database from the "Methodology applied in the Occupational Exposure Scenarios for Platinum Substances" document.

Analogous data (Ni) for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:
Identity of the substance used: Ni
Dermal exposure, local concentration on skin: Number of measured data points: 7
Explanation: The estimated exposure level (<1 µg/cm2) represents the 90th percentile of the exposure distribution for NNE in consideration of the use of appropriate gloves.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Due to the stringent conditions in place to protect for skin corrosion any other dermal adverse health effects that can be caused by HHPA-2AE are inherently prevented.
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.
Further information on the risk characterisation for all qualitative hazard conclusions is given in Section 9.0.4.

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)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

The total releases to the environment from all the exposure scenarios covered are presented in the table below. This is the sum of the releases to the environments from all exposure scenarios addressed.
Where there is more than one contributing scenario for the environment for a given exposure scenario, the highest release per route across all the contributing scenarios within the use has been taken into account as the release for the use (both for the regional and the exposure due to all the widespread uses). This may lead to overestimation of the PEC.

Table 10.1. Total releases to the environment per year from all life cycle stages

Release route	Assessment entity	Total releases per year
Water	Pt dissolved	0.714 kg/year
Air	Pt dissolved	1.8 kg/year
Soil	Pt dissolved	0 kg/year

10.2.2. Regional assessment

The regional predicted environmental concentration (PEC regional) and the related risk characterisation ratios when a PNEC is available are presented in the table below. The exposure to man via the environment from regional exposure and the related risk characterisation ratios are also provided (when relevant). The exposure concentration for human via inhalation is equal to the PEC air.
The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 10.2. Predicted regional exposure concentrations (Regional PEC) and risks for the environment

Protection target	Assessment entity	Regional PEC	Risk characterisation
Fresh water	Pt dissolved	**Regional PEC:** 3.18E-8 mg/L (estimated by External EUSES calculation 2.1.2) RCR = 2.27E-4 **Supportive exposure (not used for RC):** 2.21E-9 mg/L	Final RCR < 0.01
Sediment (freshwater)	Pt dissolved	**Regional PEC:** 8.23E-6 mg/kg dw RCR = 3.15E-5	Final RCR < 0.01
Marine water	Pt dissolved	**Regional PEC:** 2.03E-10 mg/L RCR = 1.45E-5	Final RCR < 0.01
Sediment (marine water)	Pt dissolved	**Regional PEC:** 7.57E-7 mg/kg dw RCR = 2.9E-5	Final RCR < 0.01
Agricultural soil	Pt dissolved	**Regional PEC:** 9.46E-4 mg/kg dw (Measured data: GEMAS) RCR = 0.181 **Supportive exposure (not used for RC):** 1.05E-9 mg/kg dw	Final RCR = 0.181

Remarks on exposure data from external estimation tools:

External EUSES calculation 2.1.2 for Pt dissolved:
Explanation: 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, STP removal efficiency and phys-chem properties to perform calculations of the regional PEC concentrations for freshwater . The estimated regional background PECfreshwater was then incorporated into CHESAR.

Remarks on measured exposure:

GEMAS for Pt dissolved:
Identity of the substance used: Platinum
Explanation: 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) 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 . For Pt, the mean concentrations for agricultural soil and grassland samples were 9.46 x 10-4 mg/kg d.w. and 9.26 x 10-4 mg/kg d.w., respectively. For these assessments, the mean for agricultural soil (9.46 x 10-4 mg/kg d.w.) was utilised in environmental exposure assessment.

Remarks on risk characterisation for regional concentrations:

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.

10.2.3. Local exposure due to all widespread uses

Not relevant as there are not several widespread uses covered in this CSR.

10.2.4. Local exposure due to combined uses at a site

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.

Annexes

1. Annex: References

Kuenemann, P., De Morsier, A. And Vasseur, P. 1992: Interest of carbon-balance in ready biodegradability testing (publication), Chemosphere, Vol. 24, No. 1, pp63-69.

Cobelo-Garcia A, Turner A, Millward G. 2008: Fractionation and reactivity of platinum group elements during estuarine mixing (publication), Environmental Science and Technology, 42:1096-1101.

Turner A, Crussell M, Millward G, Cobelo-Garcia A, Fisher A 2006: Adsorption kinetics of platinum group elements in river water (publication), Environmental Science and Technology, 40:1524-1531.

Sako A, Lopes L, Roychoudhury A 2009: Adsorption and surface complexation modelling of palladium, rhodium and platinum in surficial semi-arid soils and sediment (publication), Applied Geochemistry 24:86-95.

Antonelli MA 2001: Dihydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) acute oral toxicity study in the rat (acute toxic class method). (study report), Testing laboratory: Research Toxicology Centre S.p.A., Via Tito Speri, 12, 00040 Pomezia (Roma), Italy., Report no: 8742/T/266/2001. Owner company; Degussa Metals Catalysts Cerdec AG. Precious Metals Chemistry, Rodenbacher Chausse 4, D-63403 Hanau-Wolfgang, Germany., Report date: Oct 9, 2001

Spruth B 2018: In vitro skin irriation test of Ruthenium(IV) oxide in the reconstructed human epidermis model Epiderm - according to EC Method B.46 and OECD Guideline 439 (study report), Testing laboratory: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Redderweg 8, 21147 Hamburg, Germany, Report no: 35830. Owner company; European Precious Metals Federation aisbl, Avenue de Broqueville 12, 1150 Brussels, Belgium, Report date: Sep 18, 2018

Spruth B 2016: Bovine corneal opacity and permeability test of dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2) (study report), Testing laboratory: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Redderweg 8, 21147 Hamburg, Germany, Report no: 32446. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, 1150 Brussels, Belgium, Report date: Feb 12, 2016

Spruth B 2016: In vitro skin corrosion test of dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2) in the human skin model EpiDerm (study report), Testing laboratory: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Redderweg 8, 21147 Hamburg, Germany, Report no: 32940. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, 1150 Brussels, Belgium, Report date: Apr 25, 2016

Haferkorn J 2016: Skin sensitisation: local lymph node assay: BrdU-ELISA of dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2) in CBA/JN mice (study report), Testing laboratory: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Redderweg 8, 21147 Hamburg, Germany, Report no: 32447. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, 1150 Brussels, Belgium, Report date: Feb 12, 2016

Hansen B 2017: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2) concentration in rats by oral administration (study report), Testing laboratory: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Redderweg 8, 21147 Hamburg, Germany, Report no: 33688. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, 1150 Brussels, Belgium, Report date: Oct 6, 2017

Scarcella O 2001: Dihydrogen hexachloroplatinate, compound with 2-aminoethanol (1:2). Bacterial mutation assay (S.typhimurium and E.coli). (study report), Testing laboratory: Research Toxicology Centre Genetic Toxicology Department Via Tito Speri, 12 00040 Pomezia (Roma) Italy., Report no: 8741-M-04901. Owner company; Sponsor: Degussa Metals Catalysts cerdec AG Precious Metals Chemistry Rodenbacher Chaussee, 4 D-63403 Hanau - Wolfgang Germany., Report date: Oct 10, 2001

Cinelli S 2002: Dihydrogen hexachloroplatinate, compound with 2-aminoethanol (1:2). Gene mutation in Chinese hamster V79 cells. (study report), Testing laboratory: Research Toxicology Centre S.p.A. Genetic and Cellular Toxicology Department Via Tito Speri, 12 00040 Pomezia (Roma) Italy., Report no: 9397. Owner

company; Sponsor: Degussa Metals Catalysts cerdec AG Precious Metals Chemistry Rodenbacher Chaussee, 4 D-63457 Hanau - Wolfgang Germany.,

Eurlings IMJ 2020: A Combined Micronucleus and Alkaline Comet Test in the Rat with Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) (CAS 68133-90-4) (study report), Testing laboratory: Charles River Laboratories Den Bosch BV Hambakenwetering 7 5231 DD ‘s-Hertogenbosch The Netherlands Charles River Laboratories Den Bosch BV Nistelrooisebaan 3 5374 RE Schaijk The Netherlands, Owner company; European Precious Metals Federation Avenue de Broqueville 12 1150 Brussels Belgium, Study number: 20232328, Report date: Jul 17, 2020

Nau M 2018: Platin A Lösung Flash point A.9 (study report), Testing laboratory: Siemens AG Prozess-Sicherheit Industriepark Höchst, B 596 & B 598, 65926 Frankfurt am Main, Germany, Report no: PS20170469-4. Owner company; Precious Metals and Rhenium Consortium c/o European Precious Metals Federation, Avenue de Broqueville 12, 1150 Brussels, Belgium, Report date: Jan 16, 2018

Pawlowski S and Wydra V 2005: Final report. Acute toxicity of dihydrogen hexachloroplatinate IV-solution to rainbow trout (Oncorhynchus mykiss) in a 96-hour static test (study report), Testing laboratory: Institut fur Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany, Report no: 19041230. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Feb 28, 2005

Muth-Kohne E 2016: Fish acute toxicity test over 96 h under semi-static conditions (OECD TG 203, 1992) with zebrafish (Danio rerio) (study report), Testing laboratory: Fraunhofer Institute for molecular biology and applied ecology IME, Auf dem Aberg 1, 57392 Schmallenberg, Germany, Report no: WCA-010/4-32/A. Owner company; Precious metals and rhenium consortium, c/o European precious metals federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Sep 6, 2016

Par R Jouhaud, S Biagianti-Risbourg, F Arsac and G Vernet 1999: Effets du platine chez Brachydanio rerio “Teleosteen\ Cyprinide#[I[Toxicite aigue] bioaccumulation et histopathologie intestinales (publication), J Appl Ichthyol 15, 41-48. Report date: Apr 17, 1999

Shacklady LG, Mullee DM 2001: Chloro Platinic Acid: Acute Toxicity to Daphnia magna (study report), Testing laboratory: SafePharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, UK, Report no: 036/147. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: May 10, 2001

Moll M and Wydra V 2005: Final report: Acute toxicity of Dihydrogen hexachloroplatinate IV-solution to Daphnia magna in a 48-hour Immobilization Test. (study report), Testing laboratory: Institut für Biologische Analytik und Consulting IBACON GmbH, Report no: 19042220. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Jul 4, 2005

Simon M 2014: Daphnia magna, Acute Immobilization Test (OECD 202) Semi-static exposure - Effect of Hexahydroxyplatinic Acid on the immobilization of Daphnia magna (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Auf dem Aberg 1, 57392 Schmallenberg, Germany Fraunhofer IME, Report no: WCA-004/4-20/G. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Dec 12, 2014

Simon M 2014: Daphnia magna, Acute Immobilization Test (OECD 202) Static exposure - Effect of diammonium hexachloroplatinate on the immobilization of Daphnia magna (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) Auf dem Aberg 1 57392 Schmallenberg, Germany Fraunhofer IME, Report no: WCA-005/4-20/G. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Dec 11, 2014

Simon M 2016: Effect of Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol on the immobilisation of Daphnia magna (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Auf dem Aberg 1, 57392 Schmallenberg, Germany, Report no: WCA-010/4-20/G. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue

de Broqueville 12, B-1150 Brussels, Belgium, Report date: Aug 1, 2016

Okamoto A et al 2015: Acute toxicity of 50 metals to Daphnia magna (publication), J. Appl. Toxicol. 35: 824–830.

Zimmermann S et al 2017: Toxicity of platinum, palladium and rhodium to Daphnia magna in single and binary metal exposure experiments (publication), Environmental Pollution 224, 368-376.

Biesinger KE, Christensen GM 1972: Effects of Various Metals on Survival, Growth, Reproduction, and Metabolism of Daphnia magna (publication), J. Fish. Res. Bd. Canada 29: 1691-1700.

Wenzel A 2014: Freshwater Alga, Growth Inhibition Test. Effect of Hexahydroxyplatinic Acid on the Growth of Pseudokirchneriella subcapitata (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), 57392 Schmallenberg, Germany, Report no: WCA-004/4-10/A. Owner company; Precious Metals and Rhenium Consortium, c/o/ European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Dec 11, 2014

Pawlowski S and Wydra V 2005: Final report - Toxicity of Dihydrogen hexachloroplatinate IV-solution to Desmodesmus subspicatus in an Algal Growth Inhibition Test (study report), Testing laboratory: Institut fur Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany, Report no: 19043210. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Jul 3, 2005

Mead C, Mullee DM 2001: Chloro Platinic Acid: Algal Inhibition Test (study report), Testing laboratory: SafePharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, UK, Report no: 036/146. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: May 14, 2001

Wenzel A 2016: Freshwater Alga, Growth Inhibition Test (OECD 201) (study report), Testing laboratory: Fraunhofer Institute for molecular biology and applied ecology IME, Auf dem Aberg 1, 57392 Schmallenberg, Germany, Report no: WCA-010/4-10/A. Owner company; Precious metals and rhenium consortium c/o European precious metals federation, Avenue de Broqueville 12, B 1150, Brussels, Belgium, Report date: Aug 10, 2016

Sorensen S et al 2016: A Multimethod Approach for Investigating Algal Toxicity of Platinum Nanoparticles Environ. Sci. Technol. 50 (19), pp 10635–10643.

Havelkova. B et al. 2014: Impact of platinum group elements on the soil invertebrate Enchytraeus crypticus (publication), Neuroendocrinology Letters 35 (2) 101–108.

Nemcova B et al 2012: Impact of platinum on the soil invertebrate Folsomia candida (publication), Neuroendocrinology Letters Volume 33 Suppl. 3.

Muckle M 2014: Determination of the Inhibition of the Respiration of Activated Sludge when exposed to Hexahydroxyplatinic Acid according to OECD 209 resp. EU C.11 (study report), Testing laboratory: LAUS GmbH, Auf der Schafweide 20, D-67489 Kirrweiler, Germany, Report no: 14090104G701. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Dec 22, 2014

Muckle M 2015: Determination of the Inhibition of the Respiration of Activated Sludge when exposed to Hexachloroplatinic acid according to OECD 209 resp. EU C.11 (study report), Testing laboratory: LAUS GmbH, Auf der Schafweide 20, D-67489 Kirrweiler, Germany, Report no: 15061602G701. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Nov 5, 2015

Muckle M 2016: Determination of the Inhibition of the Respiration of Activated Sludge when exposed to Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol according to OECD 209 resp. EU C.11 (study report), Testing laboratory: LAUS GmbH, Auf der Schafweide 20, D-67489 Kirrweiler, Germany, Report no: 15100102G701. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Feb 24, 2016

2. Annex: Information on Test Material

Test material: **2-aminoethanol**
Form:

Composition type: Constituent	**Reference substance:** 2-aminoethanol EC no.: 205-483-3 CAS no: 141-43-5 IUPAC name: 2-aminoethanol	**Concentration range:**

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: **dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3**
Form:

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): DIhydrogen hexahydroxyplatinate compound with 2-aminoethanol (1:2) CAS 68133-90-4 - Substance type: - Physical state: Liquid - Analytical purity: - Impurities (identity and concentrations): - Composition of test material, percentage of components: - Isomers composition: - Purity test date: - Lot/batch No.: A-198-01 - Expiration date of the lot/batch: At least 6 months after analysis - Stability under test conditions: - Storage condition of test material: Opaque plastic bottle. In a dessicator at 4 deg C - Other:

Test material: **Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2); dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3**
Form: **liquid**

Composition type: Constituent	**Reference substance:** Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2)	**Concentration range:**

	EC no.: CAS no: IUPAC name: Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2)	
Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Dihydrogen hexahydroxyplatinate/2-aminoethanol (1:2) - Substance type: No data - Physical state: yellow/orange coloured liquid - Analytical purity: No data - Impurities (identity and concentrations in pmm): Ag (<0.5), Al (12), As (<10), Au (<10), Bi (<5), Ca (36), Cr (<2), Cu (<5), Fe (34.0), Ir (<3), K (<5), Mg (17.0), Mn (<1), Mo (<5), Na (3096), Ni (<5), Pd (<5), Rh (40), Ru (<7), Sb, (<15), Si (172), Sn (<5), Zn (<0.5), Cl- (1096) - Composition of test material, percentage of components: Platinum content 17.15% (w/w) - Isomers composition: Not applicable - Purity test date: 26 May 2015 - Lot/batch No.: 15135C1AES - Expiration date of the lot/batch: 25 May 2018 - Stability under test conditions: No data - Storage condition of test material: At +10°C to +25°C, kept in a tightly closed container and stored in a dry place, protected from light.

Test material: **dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3**
Form:

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Dihydrogen hexachloroplatinate, compound with 2-aminoethanol (1:2) (CAS 68133-90-4) - Substance type: - Physical state: liquid - Analytical purity: - Impurities (identity and concentrations): - Composition of test material, percentage of components: - Isomers composition: - Purity test date: - Lot/batch No.: A-198-01 - Expiration date of the lot/batch: - Stability under test conditions: not stated - Storage condition of test material: Opaque plastic bottle; In desiccator at 4 deg C - Other:

Test material: **dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2) / 68133-90-4 / 268-717-3**
Form:

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Dihydrogen hexachloroplatinate, compound with 2-aminoethanol (1:2) (CAS 68133-90-4) - Substance type: - Physical state: Liquid - Analytical purity: - Impurities (identity and concentrations): - Composition of test material, percentage of components: - Isomers composition: - Purity test date: - Lot/batch No.: A016-02 - Expiration date of the lot/batch: not stated - Stability under test conditions: not stated - Storage condition of test material: Opaque plastic bottle at room temperature - Other:

Test material: **Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol**

Form:

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**

Test material: **16941-12-1 / 241-010-7**
Form: **liquid**

Composition type: Constituent	**Reference substance:** Hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	**Concentration range:**

Details on test material: - Colour/form: orange liquid - Density: 2.069 g/mL

Test material: **Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol**
Form: **liquid**

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**

Test material: **Hexachloroplatinic acid; 16941-12-1 / 241-010-7**
Form:

Composition type: Constituent	**Reference substance:** Hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Dihydrogen hexachloroplatinate (CAS 16941-12-1) - Analytical purity: “Of the highest purity commercially available” in Japan.

Test material: **16941-12-1 / 241-010-7**
Form: **solid**

Composition type: Constituent	**Reference substance:** Hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	**Concentration range:**

Test material: **Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**
Form: **solid**

Composition type: Constituent	**Reference substance:** Hexahydroxyplatinic Acid EC no.: CAS no: IUPAC name: Hexahydroxyplatinic	**Concentration range:**

	Acid	
Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate EC no.: 257-471-2 CAS no: 51850-20-5 IUPAC name: hexahydroxyplatinate(2-)	**Concentration range:**

Details on test material: - Physical state: Yellow crystal needles - Stability under test conditions: Stable under normal conditions - Storage condition of test material: Room temperature (15-30 °C)

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.: 240-973-0 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: **Dihydrogen hexahydroxyplatinate, compound with 2-amino-ethanol**
Form: **liquid**

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) EC no.: 268-717-3 CAS no: 68133-90-4 IUPAC name: dihydrogen hexahydroxyplatinate(2-) - 2-aminoethanol (1:2)	**Concentration range:**

Test material: **Hexachloroplatinic acid (hydrate) / 26023-84-7**
Form:

Composition type: Constituent	**Reference substance:** Hexachloroplatinic acid (hydrate) EC no.: CAS no: 26023-84-7 IUPAC name: Hexachloroplatinic acid (hydrate)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Hexachloroplatinum(IV)-solution - Substance type: - Physical state: liquid - Analytical purity: - Impurities (identity and concentrations): - Composition of test material, percentage of components: 25% Pt - Isomers composition: - Purity test date: 2003-08-08 - Lot/batch No.: 2700/76-03 - Expiration date of the lot/batch: 31 July 2004 - Stability under test conditions: not stated - Storage condition of test material: room temperature; opaque plastic bottle - Other:

Test material: **Hexachloroplatinic acid**
Form: **Resin**

Composition type:	**Reference substance:**	**Concentration range:**

Constituent	Hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: Hexachloroplatinic acid	

Test material: **Hexachloroplatinic acid**
Form:

Composition type: Constituent	**Reference substance:** hexachloroplatinic acid EC no.: 241-010-7 CAS no: 16941-12-1 IUPAC name: hexachloroplatinic acid	**Concentration range:**

Test material: **Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**
Form: **solid: crystalline**

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate EC no.: 257-471-2 CAS no: 51850-20-5 IUPAC name: hexahydroxyplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Hexahydroxyplatinic Acid EC no.: CAS no: IUPAC name: Hexahydroxyplatinic 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: **Hexahydroxyplatinic Acid; hexahydroxyplatinate(2-) / 51850-20-5 / 257-471-2**
Form: **solid: crystalline**

Composition type: Constituent	**Reference substance:** dihydrogen hexahydroxyplatinate EC no.: 257-471-2 CAS no: 51850-20-5 IUPAC name: hexahydroxyplatinate(2-)	**Concentration range:**
Composition type: Constituent	**Reference substance:** Hexahydroxyplatinic Acid EC no.: CAS no: IUPAC name: Hexahydroxyplatinic Acid	**Concentration range:**

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.