CHEMICAL SAFETY REPORT

Substance Name: dipotassium hexachloropalladate
EC Number: 240-974-6
CAS Number: 16919-73-6
Registrant's Identity: Predefined Legal entity

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Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

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

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

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

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

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

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

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

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

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

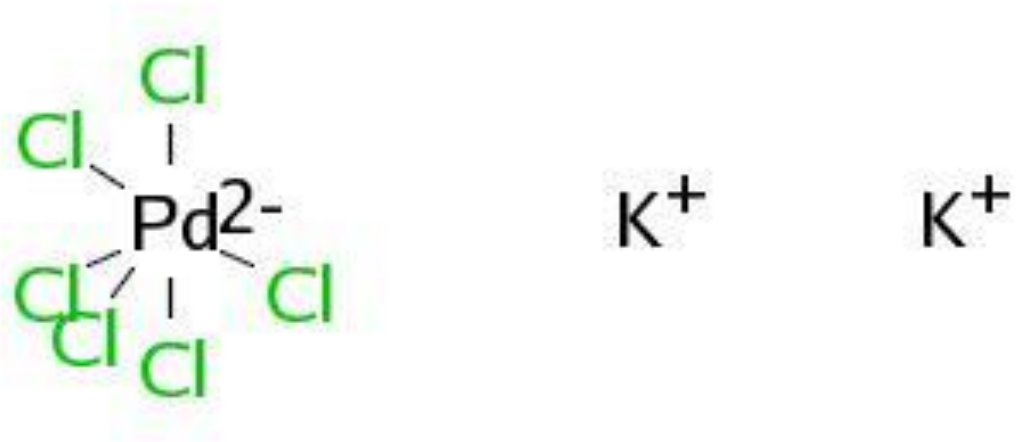
1.1. Name and other identifiers of the substance

The substance dipotassium hexachloropalladate is a mono-constituent substance (inorganic) 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:	240-974-6
EC name:	dipotassium hexachloropalladate
CAS number (EC inventory):	16919-73-6
CAS number:	16919-73-6
IUPAC name:	dipotassium hexachloropalladate(2-)
Synonyms:	Palladate(2-), hexachloro-, dipotassium, (OC-6-11)-
Molecular formula:	Cl6Pd.2K
Molecular weight range:	397.335

Structural formula:



1.2. Composition of the substance

Overall information on composition:

Composition	Related composition(s)	Related assessment entity
Dipotassium hexachloropalladate (legal entity composition of the substance)		dipotassium hexachloropalladate
Dipotassium hexachloropalladate (boundary composition of the substance)		dipotassium hexachloropalladate Pd dissolved

Name: Dipotassium hexachloropalladate

(legal entity composition of the substance)
State/form: solid and crystalline
Degree of purity: % (w/w)

Table 1.2. Constituents (Dipotassium hexachloropalladate)

Constituent	Typical concentration	Concentration range	Remarks
dipotassium hexachloropalladate EC no.: 240-974-6	% (w/w)	% (w/w)	

Table 1.3. Impurities (Dipotassium hexachloropalladate)

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

Name: Dipotassium hexachloropalladate

(boundary composition of the substance)
State/form: solid and crystalline
Degree of purity: >=99 - <=100 % (w/w)
Description: Mono-constituent substance with impurities that do not trigger a separate classification

Table 1.4. Constituents (Dipotassium hexachloropalladate)

Constituent	Typical concentration	Concentration range	Remarks
dipotassium hexachloropalladate EC no.: 240-974-6	>99 % (w/w)	>=99 - <=100 % (w/w)	The concentration range provided for dipotassium hexachloropalladate corresponds to a concentration range of 26.5 - 26.8 % palladium.

Table 1.5. Impurities (Dipotassium hexachloropalladate)

Constituent	Typical concentration	Concentration range	Remarks
Several minor impurities EC no.:	<1 % (w/w)	>=0 - <=1 % (w/w)	Several minor (especially metallic, e.g. Ag, Au, Cu, Ir, Pb, Pt, Rh, Ru) impurities which do not affect the classification of the substance because of their non-hazardous nature or because they do not exceed the classification cut-off limits in the substance.

1.3. Assessment entity information

Assessment entity name	Remarks
dipotassium hexachloropalladate	Assessment entity composition: The composition(s) for this assessment entity is the one listed in section 1.2 (Composition of the Substance)
Pd dissolved	Assessment entity composition: Palladium EC no.: Additional information: **For this category of 15 palladium substances (i.e. palladium metal and 14 inorganic palladium 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 palladium moiety / palladium complex with the formation of [Pd(OH)2]0as the dominant Pd species and a free Pd2+-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 palladium 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	**solid at 20°C and 101.3 kPa** Tremain and Atwal (2011) is a Klimisch 1, GLP-compliant study. The statement on appearance is taken from a study on the melting temperature of this material, and is adequate for the assessment as the key study for this endpoint. Dipotassium hexachloropalladate is a red solid.	Dipotassium hexachloropalladate is a red solid.	
Melting / freezing point	**450°C at 101.3 kPa** Tremain and Atwal (2011) is a GLP-compliant, guideline study which is considered suitable for use as the key study for this endpoint. Dipotassium hexachloropalladate showed no signs of melting up to 450 °C.	Dipotassium hexachloropalladate showed no signs of melting up to 450°C.	Pd dissolved

Relative density	The density of this substance is stated in two reliable secondary sources (Perry 2011 and Yaws 2005), which are considered to be suitable for use for this endpoint as part of a weight of evidence approach. Both handbooks state the density of dipotassium hexachloropalladate to be 2.738 g/cm3.	The density of dipotassium hexachloropalladate is 2.738 g/cm3.	
Granulometry	CILAS (2008) conducted particle size measurements for a sample of dipotassium hexachloropalladate. Although the study was non-GLP, the method used is considered to be suitable for the substance. The average 10th, 50th and 90th percentile particle sizes for dipotassium hexachloropalladate were 15.02, 34.40 and 56.80 µm, respectively. The average mean particle size was 35.16 µm. The dustiness of dipotassium hexachloropalladate was tested in a modified Heubach procedure according to the guideline DIN 55992-1:2006 (Selck and Parr 2011). The study is non-GLP, but follows a standard guideline and is considered to be reliable. The total dustiness of dipotassium hexachloropalladate was determined to be 588.08 mg/g. The inhalable fraction was 344.36 mg/g, the thoracic fraction was 65.74 mg/g and the respirable fraction was 5.90 mg/ g. The Mass Median Aerodynamic Diameter (MMAD) was 25.72 µm with Geometric Standard Deviation of 1.88 µm.	The average 10th, 50th and 90th percentile particle sizes for dipotassium hexachloropalladate were 15.02, 34.40 and 56.80 µm, respectively. The average mean particle size was 35.16 µm.	
Vapour pressure	**0Pa at 20°C** This is an inorganic non volatile substance. A very low value has been included for the exposure assessment.		Pd dissolved
Water solubility	**3.41g/L at 20°C** The paper Gregory (2014) is a non-GLP, modified guideline study,	The water solubility of dipotassium hexachloropalladate has been determined to be 3.41 g/L.	Pd dissolved

	available as a published report and is acceptable for use as the key study for this endpoint. The water solubility of dipotassium hexachloropalladate has been determined to be 3.41 g/L of solution using the quick shake flask method.		
Autoflammability / self-ignition temperature	Michael-Schulz (2015) is a non-GLP, guideline study and is considered reliable and suitable for use as the key study for this endpoint. Dipotassium hexachloropalladate does not fulfil the criteria of Class 4.2 “Self-heating Substances” of the UN-TDG and the Hazard Class “Self-heating Substances and Mixtures” of the Regulation (EC) No 1272/2008 (CLP-/GHS-Regulation) because no self-heating occurred in a 25 mm size cube at 195°C.	Dipotassium hexachloropalladate is not classified as a self-heating substance as no self-heating occurred in a 25 mm size cube at 195 °C.	
Flammability	**non flammable** Michael-Schulz (2015) is a non-GLP, guideline study and is considered reliable and suitable for use as the key study for this endpoint. Dipotassium hexachloropalladate does not fulfil the criteria of Class 4.1 “Flammable solids” of the UN-TDG and the Hazard Class “Flammable solids” of the Regulation (EC) No 1272/2008 (GHS/CLP) because it could not be ignited in the preliminary screening test.	Dipotassium hexachloropalladate is not classified as a flammable solid as it could not be ignited in the preliminary screening test.	
Oxidising properties	**no** The oxidising properties of dipotassium hexachloropalladate are read across from other substances with co-ordinated chloride, in the 4+ oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid). Neither of these substances are oxidising based on GLP-compliant, guideline	On the basis of read-across from test results for other substances with co-ordinated chloride, in the 4+ oxidation state (tetraammonium decachloro-mu-oxodiruthenate and hexachloroplatinic acid), dipotassium hexachloropalladate is not considered to be oxidising.	

	experimental studies (Tremain and Atwal 2011, Walker and White 2011). There is also supplementary evidence that other metal chlorides are not oxidizing. For example, other Group VIII transition metals such as cobalt (II) chloride, iron (II), iron(III) and nickel(II) chloride. Copper(I) chloride from the adjacent Group IB is also not classified for oxidizing properties. There is therefore no evidence that any transition metal chloride is an oxidant. Supplementary evidence also comes from the non-transition metal chlorides and there is no evidence from two centuries of industrial and academic experience that these substances are oxidants. On the basis of read-across dipotassium hexachloropalladate is not classified as an oxidising solid.		

Data waiving

Information requirement: Boiling point

Reason: study scientifically not necessary / other information available

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

Information requirement: Vapour pressure

Reason: study scientifically not necessary / other information available

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

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

Reason: study technically not feasible

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

Information requirement: Surface tension

Reason: study scientifically not necessary / other information available

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

Information requirement: Flash point

Reason: study technically not feasible

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

Information requirement: Explosive properties

Reason: study scientifically not necessary / other information available

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

Discussion of physicochemical properties

Additional information:

Physico-chemical endpoints for this substance are filled using proprietary data, published data, test data generated as part of the REACH registration process and appropriate data waivers.

On the basis of the available physico-chemical data this substance 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: Dipotassiumhexachloropalladate is produced as an isolated intermediate in the Refining process of palladium. It is obtained by secondary sources. The starting point is a hydrochloric acidic solution of Tetrachloropalladate, which is saturated with chlorine to oxidize Palladium from +II to +IV. Potassium chloride is added to the solution and Dipotassiumhexachloropalladate precipitates as a red, fine/coarse powder. The Dipotassiumhexachloropalladate is filtrated and will be used afterwards in the refining process of Palladium. The salt is 90-99 % pure. Dipotassiumhexachloropalladate as pure substance is obtained in a two-step reaction by dissolving Pd sponge in hydrochloric acid with Chlorine as oxidizing agent and by addition of Potassium Chloride to the chlorine saturated solution afterwards. The salt precipitates as a fine powder. 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)** **- Manufacture of the substance (as such) ES 1.3 (ERC1)** Contributing activity/technique for the workers : **- Wet chemistry in open or semi-closed processes (PROC 4)** **- Handling of solutions/Wet chemistry in open or semi-closed processes (PROC 4)** **- Fully contained processes (PROC 1)** **- Manual handling of low dusty materials (PROC 26)** **- Manual handling of dusty materials (PROC 26)** **- Wet cleaning (PROC 8a)** **- Vacuum cleaning (PROC 26)** 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)** **- Use as an intermediate ES 2.3 (ERC6a)** Contributing activity/technique for the workers : **- Raw material handling (PROC 26)** **- Open or semi-closed wet chemical reaction process (PROC 4)** **- Wet cleaning (PROC 8a)**

	- Vacuum cleaning (PROC 26) **Sector of end use:** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) **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
IW-2	**Use as an intermediate in the catalyst industry** Further description of the use: Contributing activity/technique for the environment : **- Use as an intermediate in the catalyst industry (ERC6a)** Contributing activity/technique for the workers : **- Raw material handling (PROC 26)** **- Fully contained process (PROC 1)** **- Closed batch process (PROC 3)** **- Small scale handling/transfer of solutions (PROC 9)** **- Laboratory analyses (PROC 15)** **- Wet cleaning (PROC 8a)** **- Vacuum cleaning (PROC 26)** **Sector of end use:** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) ; SU 9: Manufacture of fine chemicals **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: Dipotassium hexachloropalladate
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:	Acute Tox. 4	H302: Harmful if swallowed.	
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:	Skin Irrit. 2	H315: Causes skin irritation.	
Serious damage / eye irritation:	Eye Damage 1	H318: Causes serious eye damage.	
Respiratory sensitisation:			data lacking
Skin sensitisation:	Skin Sens. 1B	H317: May cause an allergic skin reaction.	
Aspiration hazard:			data lacking
Reproductive Toxicity:			data conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:			data conclusive but not sufficient for classification
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:			data lacking
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: 10			
M-Factor chronic: 10			
Hazardous to the ozone layer:			data conclusive but not sufficient for classification

Labelling

Signal word: Danger

Hazard pictogram:

GHS05: corrosion

GHS07: exclamation mark

GHS09: environment

Hazard statements:

H302: Harmful if swallowed.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H318: Causes serious 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.

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

P264: Wash ... thoroughly after handling.

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

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

P273: Avoid release to the environment.

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

P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.

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

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

P310: Immediately call a POISON CENTER/doctor/…

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

P330: Rinse mouth.

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

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

P391: Collect spillage.

P501: Dispose of contents/container to ...

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

The log Kd for suspended particulate matter (SPM) in freshwater is 3.39 (stdev 0.40) and the average Kd is 2455 L/kg. Where wastewater is discharged to marine water it is recommended to use the measured partition coefficient in seawater, log Kd 4.21 (i.e. Kd is 16220 L/kg). The log Kd for soil is 2.64 (stdev 0.48) and the average Kd is 436.5 L/kg.

Additional information:

Information on the partitioning of palladium in the environment is taken from three published papers (Cobelo-Garcia et al. 2008, Sako et al. 2009, Turner et al. 2006) and Kd values have been calculated for suspended particulate matter in freshwater, seawater and soil.

Biodegradation and hydrolysis are not considered to be relevant endpoints for this substance.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

No relevant information available.

Data waiving

Information requirement: Hydrolysis

Reason: study scientifically not necessary / other information available

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

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available.

4.1.1.2.2. Phototransformation in water

No relevant information available.

4.1.1.2.3. Phototransformation in soil

No relevant information available.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

No relevant information available.

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: study technically not feasible

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

4.1.2.1.2. Simulation tests (water and sediments)

No relevant information available.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

No relevant information available.

4.1.2.2. Biodegradation in soil

No relevant information available.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

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

Table 4.1. Studies on adsorption/desorption

Method	Results	Remarks
adsorption / desorption [deactivated phrase] - adsorption batch equilibrium method Laboratory study, no guideline followed	Adsorption coefficient: log Kd: 3.59 at 23°C (Mean for all salinities, standard deviation 0.41) log Kd: 3.39 at 23°C (Mean for freshwaters, standard deviation 0.40) log Kd: 3.84 at 23°C (Mean for estuarine waters, standard deviation 0.04) log Kd: 4.21 at 23°C (Single value for seawater, salinity 33 %) 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** Palladium (II), Form: gas under pressure: refrigerated liquefied gas (full information in **Annex II**). **Reference** **Cobelo-Garcia A, Turner A, Millward G. 2008**
adsorption / desorption [deactivated phrase] - adsorption batch equilibrium method Laboratory study, no guideline followed	Adsorption coefficient: log Kd: 2.64 at 25°C (Overall mean, standard deviation 0.48) 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** Palladium (II), Form: gas under pressure: refrigerated liquefied gas (full information in

		Annex II). **Reference** **Sako A, Lopes L, Roychoudhury A 2009**
adsorption / desorption [deactivated phrase] - adsorption batch equilibrium method Laboratory study, no guideline followed	Adsorption coefficient: log Kd: >2.7 - <3 at 20°C (Dependent on treatment of the sediment material) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) supporting study experimental study **Test material** Palladium (II), 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**

Discussion

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

The log Kd for suspended particulate matter (SPM) in freshwater is 3.39 (stdev 0.40) and the average Kd is 2455 L/kg. Where wastewater is discharged to marine water it is recommended to use the measured partition coefficient in seawater, log Kd 4.21 (i.e. Kd is 16220 L/kg). The log Kd for soil is 2.64 (stdev 0.48) and the average Kd is 436.5 L/kg. 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 soil) : 2.64 at 25°C

log Kp (solids-water in suspended matter) : 3.39 at 23°C

log Kp (solids-water in sediment) : 3.39 at 23°C

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

Additional information:

Two high quality studies have determined the partitioning of Pd 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 palladium 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 across all waters studied is 3.59 and the average Kd across all salinities is 3890.5 L/kg (st dev 0.41). Averaging of Kd values obtained from tests at different salinities hides a clear difference in the partitioning behaviour of palladium between fresh and marine waters, with stronger partitioning being observed in marine water. Consequently, separate Kd values are recommended for assessments of freshwater and marine systems. The log Kd for freshwater is 3.39 (stdev 0.40) and the average Kd is 2455 L/kg. The log Kd for marine water is 4.21, and the Kd is 16220 L/kg. The log Kd for soil is 2.64 (stdev 0.48) and the average Kd is 436.5 L/kg.

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:

With its relatively low molecular weight (~400 g/mol) and, more critically, relatively high water solubility (3.41 g/L), it is likely that dipotassium hexachloropalladate will be absorbed (as the ions) from the gastro intestinal tract. As such, predicted oral absorption of dipotassium hexachloropalladate is conservatively set at 100%.

Although not expected to reach the lungs in appreciable quantities (based on respiratory tract deposition modelling data), as a water soluble substance with a relatively low molecular weight, any dipotassium hexachloropalladate reaching the lungs is likely to be absorbed through aqueous pores. As such, the predicted inhalation absorption is conservatively set at 100%.

With a water solubility of 3.41 g/L, dipotassium hexachloropalladate may be unable to cross the lipid rich environment of the stratum corneum, given the low dermal penetration expected from metals. However, dipotassium hexachloropalladate is classified as a skin irritant. This irritant potential may disrupt skin barrier function, facilitating dermal penetration. As such, predicted dermal absorption is conservatively set at 100%.

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

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

Additional information:

Absorption

Good-quality information on absorption of palladium compounds is very limited. In general, a compound needs to be dissolved before it can be taken up from the gastro-intestinal tract after oral administration. Experts from the IPCS reported that absorption of palladium ions from the gastrointestinal tract is poor, a view based on a study where adult and suckling rats absorbed less than 0.5% and about 5%, respectively, of a single oral dose of radiolabelled (103Pd) palladium dichloride (IPCS, 2002). Experts from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) used an oral absorption figure of 10% when converting an oral permitted daily exposure figure for palladium compounds to a parenteral equivalent (ICH, 2014). Based on expert ECHA guidance, the relatively low molecular weight (~400 g/mol) and, more critically, the relatively high estimated water solubility (3.41 g/L; Gregory, 2014) are indicative of a high bioavailability of dipotassium hexachloropalladate (as ions) by this route. A health-precautionary assumption is that the ions will be well-absorbed from the gastro-intestinal tract. As such, predicted oral absorption of dipotassium hexachloropalladate is set at 100%.

In the acute oral toxicity test on dipotassium hexachloropalladate, findings in the lungs and spleen at necropsy (Zechel, 1990) indicated at least partial oral absorption. No conclusions about absorption could be reached from a 28-day oral study on the structurally related compound diammonium hexachloropalladate, because the adverse findings (histological inflammation of the stomach and elevated mean white blood cell counts) were considered to reflect a local irritant effect rather than systemic toxicity (Matting, 2015), or from a repeated-dose oral reproduction toxicity study (where similar local effects were observed in the stomach of parental animals) (Török-Bathó, 2015).

No good-quality data were found regarding absorption of palladium compounds following inhalation. One Expert Group noted that, following a single intratracheal or inhalation (7.2 mg/m3; aerodynamic diameter around 1 µm) exposure to 103Pd-radiolabeled palladium dichloride in rats, absorption/retention was higher than was observed for oral administration (i.e. >5%) but did not differentiate between absorption and mere retention in the respiratory tract (IPCS, 2002). Vapour pressure testing was waived on the basis of dipotassium hexachloropalladate having a high melting point (no signs of melting at up to 450°C; Tremain, 2011b). Particle size distribution (PSD) data indicates that a significant proportion of the compound is <100 µm, based on average 10th, 50th and 90th percentile particle sizes of 15.0, 34.4 and 56.8 µm, respectively, and an average mean particle size of 35.16 µm (CILAS, 2008a,b). Further, dustiness testing, a more energetic PSD measurement, with the compound returned a mass median aerodynamic diameter (MMAD) value of 25.7 µm (Parr, 2011; Selck and Parr, 2011), indicating that a significant proportion of the substance is likely to be inhalable. However, respiratory tract deposition modelling with the dustiness data yielded output values of 52.5, 0.17 and 0.15% for the nasopharyngeal (head), tracheobronchial (TB) and pulmonary regions of the respiratory tract, respectively. This indicates that very little airborne substance (<1%) will be deposited in the lower regions of the human respiratory tract, i.e. the TB or pulmonary regions via oronasal normal augmenter breathing.

Most of the inhaled fraction is likely to be retained in the head region and therefore would be cleared by ingestion, along with that deposited in the TB region, and oral bioavailability will again predominantly determine systemic uptake. Less than 1% is likely capable of reaching the alveoli. Thus, inhalation will not be a significant route of exposure. However, as a relatively water soluble substance (3.41 g/L), any dipotassium hexachloropalladate reaching the lungs is likely to be absorbed through aqueous pores or be retained in the mucus and transported out of the respiratory tract. Overall, while it is very unlikely that dipotassium hexachloropalladate will be available to a high extent via the lungs, it is considered health precautionary to take forward the ECHA default inhalation absorption value of 100%.

No good-quality data were found regarding absorption following dermal exposure to palladium compounds. One Expert Group noted that “palladium was found in all internal organs examined” after dermal treatment of rabbits with “palladium hydrochloride” (formula not specified) or guinea pigs with chloropalladosamine, but quantitative absorption data were not given (IPCS, 2002). Estimation of dermal absorption is based on relevant available information (mainly water solubility, molecular weight and log Pow) and expert judgement. Partition coefficient testing was waived on the basis of the inorganic nature of substance. However, given the water soluble nature of dipotassium hexachloropalladate (3.41 g/L), it may be able to cross the lipid-rich environment of the stratum corneum to a “moderate to high” extent (ECHA, 2014). In the light of the limited available experimental data, ECHA guidance indicates that a default value of 100% dermal absorption should be used (ECHA, 2014). However, specific guidance on the health risk assessment of metals indicates that molecular weight and log Pow considerations 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 tentatively proposes dermal absorption figures: 1.0 and 0.1% following exposure to liquid/wet media and dry (dust) respectively (ICMM, 2007). Nevertheless, dipotassium hexachloropalladate is

classified as a skin irritant. This is based on the observation of moderate skin irritation in rabbits (Zechel, 1989a). Such irritant potential may disrupt skin barrier function, facilitating dermal penetration. As such, it is considered health precautionary to take forward the ECHA default dermal absorption value of 100%.

No signs of systemic toxicity were seen in an in vivo skin irritation study on dipotassium hexachloropalladate (Zechel, 1989a) following dermal exposure, or in a skin sensitisation study on the structurally related compound diammonium hexachloropalladate (Valiczko, 2013). Given that toxicity was evident after oral exposure, this provides limited support for the conclusion that dipotassium hexachloropalladate will not be well absorbed dermally.

Distribution/Metabolism

Once absorbed, distribution of potassium and hexachloropalladate ions throughout the body is expected based on a relatively low molecular weight.

In the acute oral toxicity test on dipotassium hexachloropalladate, necropsy of deceased animals revealed findings in the lungs and spleen (Zechel, 1990), suggesting possible distribution to these organs.

When rats were given potassium hexachloropalladate in the drinking water at 0, 10, 100 or 250 mg/L for 90 days, absorbed Pd was found mainly in the kidneys and it did not accumulate in liver, lung, spleen or bone tissue (Iavicoli et al., 2010). IPCS noted that, after single oral, intravenous or intratracheal doses of palladium salts or complexes to rats, rabbits or dogs, the highest palladium concentrations were found in kidney, liver, spleen, lymph nodes, adrenal gland, lung and bone (IPCS, 2002).

Elimination

In rats given potassium hexachloropalladate in the drinking water at up to 250 mg/L for 90 days, elimination was rapid and primarily through the faecal route, although small amounts were found in the urine at the highest dose level (Iavicoli et al., 2010).

Despite having a molecular weight above 300 g/mol (molecular weights below this figure are considered to be associated with favourable excretion in the rat (ECHA, 2014)), rapid excretion is likely based on a relatively high water solubility. It is noted that certain metals and ions may interact with the matrix of the bone, causing them to accumulate within the body (ECHA, 2014). However, dipotassium hexachloropalladate is considered to have only a low potential for bioaccumulation based on its predicted physico-chemical properties (i.e. water solubility of 3.41 g/L).

Conclusion

Based on the physico-chemical properties, the chemical structure, molecular weight and the results of toxicity studies, as well as limited toxicokinetic data on other palladium compounds, dipotassium hexachloropalladate is likely partially bioavailable by the oral route and rapidly excreted once absorbed. A high dermal bioavailability is unlikely, particularly as the substance is an inorganic solid. Nevertheless, its irritant potential may disrupt skin barrier function, facilitating dermal penetration. Although bioavailability by the inhalation route is anticipated to be low (based on respiratory tract deposition modelling data, inhalation absorption is considered a possibility based on its low molecular weight and relatively high water solubility. Proposed predicted absorption figures for the oral, dermal and inhalation routes are all conservatively set at 100%.

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] (Bor: WISW (SPFCpb)) male/female oral: gavage according to OECD Guideline 401 (Acute Oral Toxicity) [before 2002]	LD50: ca.1448 mg/kg bw (male/female) (Probit analysis) LD50: ca.1358 mg/kg bw (female) (Probit analysis) LD50: ca.1562 mg/kg bw (male) (Probit analysis)	1 (reliable without restriction) key study experimental study **Test material** dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Zechel H.J 1990**

5.2.1.2. Acute toxicity: inhalation

No relevant information available.

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: other justification

Justification: see 'Remark' - In accordance with Column 2 of REACH Annex VIII, this study does not need to be conducted as human exposure via inhalation of aerosols, particles or droplets of an inhalable size is very unlikely. Particle size distribution (PSD) data indicates that a significant proportion of dipotassium hexachloropalladate is <100 µm, based on average 10th, 50th and 90th percentile particle sizes of 15.0, 34.4 and 56.8 µm, respectively, and an average mean particle size of 35.16 µm (CILAS, 2008a,b). Dustiness testing, a more energetic PSD measurement, with the compound returned a mass median aerodynamic diameter (MMAD) value of 25.7 µm. An MMAD value <100 µm indicates that a significant proportion of a substance is likely to be inhalable. Respiratory tract deposition modelling with the dustiness data yielded output values of 52.5, 0.17 and 0.15% for the nasopharyngeal (head), tracheobronchial (TB) and pulmonary regions of the respiratory tract, respectively. Hence, very little airborne substance (<1%) is expected to deposit in the lower regions of the human respiratory tract, i.e. the TB or pulmonary regions via oronasal normal augmenter breathing. Most of the inhaled fraction is likely to be retained in the head region and therefore would be cleared by ingestion. Particles deposited in the TB region are also largely translocated to the gastrointestinal tract, and oral bioavailability will again predominantly determine systemic uptake. Thus, inhalation will not be a significant route of exposure. Further, dipotassium hexachloropalladate is classified as a skin sensitiser. Given that skin sensitisation may be acquired by other routes of exposure than dermal, appropriate risk management measures/operational controls (RMMs/OCs) are required. These will ensure that the potential for inhalation exposure is minimised. Finally, for animal welfare reasons, conducting new in vivo toxicity tests is considered a last resort. Consequently, no testing by the inhalation route is considered justified.

5.2.1.3. Acute toxicity: dermal

No relevant information available.

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: study scientifically not necessary / other information available

Justification: see 'Remark' - No acute dermal toxicity data are available. The existing in vivo skin irritation study on dipotassium hexachloropalladate (Zechel, 1989a), albeit limited in its assessment of systemic toxicity, indicates a lack of acute systemic toxicity following dermal exposure. No skin sensitisation study was conducted on dipotassium hexachloropalladate. However, no signs of general systemic toxicity were apparent in the skin sensitisation study on the structurally related compound diammonium hexachloropalladate (Valiczko, 2013). Exposure considerations provide good support for the conclusion that an acute dermal toxicity study can be waived. First, dipotassium hexachloropalladate is a solid (Tremain and Atwal, 2011) and skin contact during production and/or use is expected to be very low. Second, dipotassium hexachloropalladate is classified for skin irritation and eye damage, and as a skin sensitiser, so appropriate safety labelling, personal protection and RMMs/OCs are required. These will ensure that the potential for skin exposure is minimised. As such, there are sufficient available data for chemical hazard and risk assessment, classification and labelling, and risk mitigation purposes. Further, specific guidance on the health risk assessment of metals (ICMM, 2007) indicates low dermal absorption (up to 1.0%). Finally, for animal welfare reasons, conducting new in vivo toxicity tests is considered as a last resort. As such, no further testing is considered justified.

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 a GLP study, conducted according to OECD guidelines, the acute oral LD50 of dipotassium hexachloropalladate in the rat has been calculated as 1448 mg/kg bw (Zechel, 1990).

No acute inhalation or dermal toxicity data were identified (for dipotassium or diammonium hexachloropalladate).

Value used for CSA:
Acute oral toxicity:
adverse effect observed
(LD50) 1448mg/kg bw
Acute dermal toxicity:
no study available
Acute inhalation toxicity:
no study available

Additional information:

No human data were identified for acute exposure (for dipotassium or diammonium hexachloropalladate).

In a GLP study conducted according to OECD Test Guideline 401, five rats/sex/group were treated with 1000, 1470 or 2150 mg/kg bw dipotassium hexachloropalladate by stomach tube, and observed for 14 days (although

one animal was observed for 21 days). Two males and four females in the mid-dose group died within six days; all animals in the high-dose group died within seven days. Toxic effects included neurotoxicity, local irritant effects on the digestive organs and lung damage. The study authors calculate (using probit analysis) that the acute oral median lethal dose (LD50) is 1562 mg/kg bw in male rats (95% CI 1123-2249 mg/kg bw), 1358 mg/kg bw in female rats (95% CI 924-1182 mg/kg bw) and 1448 mg/kg bw for both sexes combined (95% CI 1234-1696 mg/kg bw) (Zechel, 1990).

Based on the results of this study, dipotassium hexachloropalladate should be classified for acute oral toxicity (category 4) according to EU CLP criteria (EC 1272/2008).

No acute inhalation toxicity data were identified (for dipotassium or diammonium hexachloropalladate). However, dipotassium hexachloropalladate is not expected to reach the lungs in appreciable quantities (based on respiratory tract deposition modelling data). Thus, inhalation will not be a significant route of exposure.

Similarly, no acute dermal toxicity data were identified (for dipotassium or diammonium hexachloropalladate). However, skin contact during production and/or use is expected to be negligible.

Justification for selection of acute toxicity – oral endpoint
GLP study, conducted according to OECD guidelines, and the only acute oral toxicity study available.

Justification for classification or non classification:

Based on the results of the available reliable acute oral rat study, dipotassium hexachloropalladate should be classified for acute oral toxicity (category 4) according to EU CLP criteria (EC 1272/2008).

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

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

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

Table 5.2. Studies on skin irritation

Method	Results	Remarks
rabbit [common species] (White Russian (albino)) Coverage: occlusive (Backs of the rabbits were clipped one day before treatment.) Vehicle: water - [demineralized; to moisten test material only] according to OECD Guideline 404 (Acute Dermal Irritation / Corrosion) ; according	Category 2 (irritant) - Migrated information Criteria used for interpretation of results: EU erythema score ([It was not possible to assess the degree of redness (erythema) resulting from exposure due to discolouration of the skin by the test substance])	2 (reliable with restrictions) key study experimental study **Test material** dipotassium hexachloropalladate(

to EU Method B.4 (Acute Toxicity: Dermal Irritation / Corrosion)	edema score 1 of max. 4 (Time point: 1, 24, 48 and 72 hours after termination of exposure) Reversibility: fully reversible within: 7 days (The maximum oedema score was seen in a single animal 24 hours post-application.)	2-) / 16919-73-6 / 240-974-6, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Zechel H.-J. 1989**
rabbit [common species] (albino) Coverage: occlusive (Pairs of test sites, each 2 cm x 2 cm, on the closely clipped dorsolaterals aspects of each animal, one side abraded and the other side intact) Vehicle: water - 0.1 ml no guideline followed Dermal irritancy assessed using male albino rabbits using procedures and evaluation criteria adopted from those in use by the National Institute for Occupational Safety and Health, ... a modification of the official Food and Drug Administration procedure [1973]"	not irritating - Migrated information to intact skin Criteria used for interpretation of results: other: evaluation criteria adopted from those in use by the National Institute for Occupational Safety and Health overall irritation score 0 of max. 4 (Time point: 24 and 72 hours) (Severity rating for intact skin site) overall irritation score - Most severe test result observed 0 of max. 4 (Time point: 24 and 72 hours) (Severity rating for intact skin site) overall irritation score 1.6 of max. 4 (Time point: 24 and 72 hours) Reversibility: no data (Severity rating for abraded skin site) overall irritation score - Most severe test result observed 2 of max. 4 (Time point: 24 and 72 hours) Reversibility: no data (Severity rating for abraded skin site)	2 (reliable with restrictions) supporting study experimental study **Test material** dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6, (full information in **Annex II**). **Reference** **Campbell KI et al. 1975**

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

Data waiving

Information requirement: Skin Irritation

Reason: study scientifically not necessary / other information available

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

5.3.1.2. Human information

No relevant information available.

5.3.2. Eye

5.3.2.1. Non-human information

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

Table 5.3. Studies on eye irritation

Method	Results	Remarks
rabbit (White Russian (albino)) Vehicle: unchanged (no vehicle) according to OECD Guideline 405 (Acute Eye Irritation / Corrosion) ; according to EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion)	corrosive - Migrated information Criteria used for interpretation of results: expert judgment overall irritation score reversibility was not assessed due to humane sacrifice of the animal one hour after application of the test substance. An irritation index could not be determined because of the corrosive effects of the test substance.	1 (reliable without restriction) key study experimental study **Test material** dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Zechel H.-J. 1989**

Data waiving

Information requirement: Eye Irritation

Reason: study scientifically not necessary / other information available

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

5.3.2.2. Human information

No relevant information available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No relevant information available

5.3.3.2. Human information

No relevant information available.

5.3.4. Summary and discussion of irritation

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

In an OECD Guideline study, to GLP, the irritant effect of dipotassium hexachloropalladate to the skin of rabbits was described as of “only slight to moderate intensity”. It was not possible to assess the degree of redness (erythema) resulting from exposure due to discolouration of the skin by the test substance, but the oedema score indicates that this is probably a reasonable conclusion (Zechel, 1989a).

In an OECD Guideline study, to GLP, undiluted dipotassium hexachloropalladate (90 mg) produced severe irritation and corrosive effects following instillation into the eye of one male rabbit (Zechel, 1989b).

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

Additional information:

No human data were identified for irritation (for dipotassium or diammonium hexachloropalladate). No in vitro skin or eye irritation studies were identified, or are required, as reliable in vivo studies are already available.

In a GLP skin irritation study in rabbits,conducted according to OECD Test Guideline 404, dipotassium hexachloropalladate (0.5 g, moistened) was applied (occluded) to the clipped but intact skin of one male and two female rabbits. After 4 hours, the dressings were removed and the skin sites gently washed. Each site was quantitatively assessed for oedema at 1, 24, 48 and 72 hours (and subsequently once/day up to 10 days post-application). Erythema and eschar formation could not be assessed quantitatively or qualitatively because the test material caused yellow or orange discolouration of the application site. Consequently the calculation of a primary irritation index was not possible. The authors concluded that the irritant effects of this material were of "only slight to moderate intensity" (Zechel, 1989a).

Due to the skin site discolouration, it is not possible to give a definitive classification interpretation according to EU CLP criteria (EC 1272/2008). However, it is considered precautionary to classify the test material as a skin irritant (Category 2).

Neat dipotassium hexachloropalladate was not irritant when applied to the intact skin of rabbits in a limited, non-GLP, study (Campbell et al., 1975). This supports an EU CLP skin classification in category 2, as a health precautionary approach.

In an OECD Guideline study, to GLP, undiluted dipotassium hexachloropalladate (90 mg) was instilled into one eye of one rabbit and both lids were briefly closed by gentle finger pressure. The other eye remained untreated and acted as the control. Following application of the test material, severe changes indicative of a corrosive effect were seen within one hour that necessitated humane sacrifice of the animal. These included opacity and necrosis of the cornea, profuse ocular discharge and swelling and necrosis in the conjunctiva and nictitating membrane. An irritation index could not be determined because of the corrosive effects. No systemic toxicity was seen (Zechel, 1989b).

As the results were based on only one rabbit, it is not possible to give a definitive interpretation according to EU CLP criteria (EC 1272/2008). However, it is considered prudent to classify the test material for serious eye damage (Category 1), as the severe effects observed are not expected to be reversible.

No respiratory tract data were identified. A new study was not conducted as it is not a REACH Standard Information Requirement. Further, the compound is not expected to reach the lungs in appreciable quantities (based on respiratory tract deposition modelling data). Thus, inhalation will not be a significant route of exposure.

Justification for selection of skin irritation / corrosion endpoint:
GLP study, conducted according to OECD guidelines.

Justification for selection of eye irritation endpoint:
GLP study, similar to OECD guidelines, and the only eye irritation study available.

Justification for classification or non classification:

Based on the results of the available skin and eye irritation studies (in rabbits), dipotassium hexachloropalladate should be classified as a skin irritant (category 2) and for eye damage (category 1), according to EU CLP criteria (EC 1272/2008).

5.4. Corrosivity

5.4.1. Non-human information

No relevant information available.

Data waiving

Information requirement: Skin irritation

Reason: study scientifically not necessary / other information available

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

5.4.2. 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 5.4. Studies on skin sensitisation

Method	Results	Remarks
mouse (CBA/J Rj) female skin sensitisation: in vivo (LLNA)	sensitising - Migrated information Criteria used for interpretation of results: EU	1 (reliable without restriction) key study

according to OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay)	Stimulation index: (The stimulation index values were 10.6, 14.9 and 1.3 at concentrations of 50, 25 and 10 % (w/v), respectively. Also see Table 1 in "Any other information on results incl. tables".) disintegrations per minute (DPM): (See Table 1 in "Any other information on results incl. tables".)	experimental study **Test material** diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9, Form: solution (full information in **Annex II**). **Reference** **Váliczkó É 2013**
mouse (CBA/J Rj) female skin sensitisation: in vivo (LLNA) according to OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay)	sensitising - Migrated information Criteria used for interpretation of results: EU Stimulation index: (The stimulation index values were 10.6, 14.9 and 1.3 at concentrations of 50, 25 and 10 % (w/v), respectively. Also see Table 1 in "Any other information on results incl. tables".) disintegrations per minute (DPM): (See Table 1 in "Any other information on results incl. tables".)	1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) **Test material** dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6, Form: not specified (full information in **Annex II**). **Reference** **Váliczkó É 2013**
Justification for type of information: Diammonium and dipotassium hexachloropalladate are considered to fall within the scope of the read-across category "hexachloropalladate salts". See section 13 for full justification report.		

Data waiving

Information requirement: Skin Sensitisation

Reason: study scientifically not necessary / other information available

Justification: an in vitro skin sensitisation study does not need to be conducted because adequate data from an in vivo skin sensitisation study are available [study scientifically not necessary / other information 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 LLNA, performed according to OECD Test Guideline 429, significant evidence (a calculated EC3 value of 11.9%) for the skin sensitising potential of diammonium hexachloropalladate was reported (Váliczkó, 2013).

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

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

The skin sensitising potential of diammonium hexachloropalladate has been assessed in a GLP mouse local lymph node assay (LLNA), performed according to OECD Test Guideline 429. Following a preliminary range-finding study to assess irritancy, female mice (5/group) were treated topically with 0, 10, 25 or 50% diammonium hexachloropalladate (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 tritiated methyl thymidine (3HTdR). No mortality or clinical signs of toxicity were observed, and there were no signs of local irritation at the application site. Observed stimulation index values were 10.6, 14.9 and 1.3 at 50, 25 and 10%, respectively. The calculated EC3 value (the concentration producing a stimulation index of 3) was 11.9%. Positive and vehicle controls performed as expected (Váliczkó, 2013). Diammonium hexachloropalladate is considered to fall within the scope of the read-across category “hexachloropalladate salts”. See section 13 for full justification report.

Migrated from Short description of key information:
In a GLP mouse LLNA, performed according to OECD Test Guideline 429, significant evidence (a calculated EC3 value of 11.9%) for the skin sensitising potential of diammonium hexachloropalladate was reported (Váliczkó, 2013).

Justification for selection of skin sensitisation endpoint:
GLP study, conducted according to OECD guidelines, and the only skin sensitising study available.

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 (for dipotassium or diammonium hexachloropalladate). A new study was not conducted as no standard and validated test method is available and it is not a REACH Standard Information Requirement. Further, the compound is not expected to reach the lungs in appreciable quantities (based on respiratory tract deposition modelling data). Thus, inhalation will not be a significant route of exposure.

Migrated from Short description of key information:
No respiratory tract sensitisation data are available (for dipotassium or diammonium hexachloropalladate).

Justification for classification or non classification:

Based on the results of the available and reliable mouse LLNA on diammonium hexachloropalladate, dipotassium hexachloropalladate should also be classified as a skin sensitiser (category 1B) 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 5.5. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks
rat [common rodent species] (Wistar [rat]) male/female short-term repeated dose toxicity: oral (oral: gavage) Vehicle: corn oil Exposure: 28 consecutive days (formulations were administered once daily by oral gavage) according to OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents) ; according to EU Method B.7 (Repeated Dose (28 Days) Toxicity (Oral))	NOAEL - systemic toxicity: 100 mg/kg bw/day (nominal) (male/female) based on: (test mat.) No systemic toxicity was observed. Treatment related effects in the high dose group were considered to reflect a local irritant effect of the test substance rather than systemic toxicity. NOAEL - local effects: 30 mg/kg bw/day (nominal) (male/female) based on: (test mat.) see 'Remark' - Multifocal dark red discolouration of the glandular stomach mucosa in male animals of the high (100 mg/kg bw/day) dose group, with associated histological inflammatory changes of the gastric mucosa and a statistically significant increase in white blood cell count. Similar inflammatory changes were evident histopathologically at a lower incidence in some females in the high dose group.	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Matting, E. 2015**
rat [common rodent species] (Wistar [rat]) male/female	NOAEL - systemic toxicity: 100 mg/kg bw/day (nominal) (male/female) based	2 (reliable with restrictions)

short-term repeated dose toxicity: oral (oral: gavage) Vehicle: corn oil Exposure: 28 consecutive days (formulations were administered once daily by oral gavage) according to OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents) ; according to EU Method B.7 (Repeated Dose (28 Days) Toxicity (Oral))	on: (test mat.) No systemic toxicity was observed. Treatment related effects in the high dose group were considered to reflect a local irritant effect of the test substance rather than systemic toxicity. NOAEL - local effects: 30 mg/kg bw/day (nominal) (male/female) based on: (test mat.) see 'Remark' - Multifocal dark red discolouration of the glandular stomach mucosa in male animals of the high (100 mg/kg bw/day) dose group, with associated histological inflammatory changes of the gastric mucosa and a statistically significant increase in white blood cell count. Similar inflammatory changes were evident histopathologically at a lower incidence in some females in the high dose group.	key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloropalladate, (full information in **Annex II**). **Reference** **Matting, E. 2015**
Justification for type of information: Diammonium and dipotassium hexachloropalladate are considered to fall within the scope of the read-across category "hexachloropalladate salts". See section 13 for full justification report.		

5.6.1.2. Repeated dose toxicity: inhalation

No relevant information available.

5.6.1.3. Repeated dose toxicity: dermal

No relevant information available.

5.6.1.4. Repeated dose toxicity: other routes

No relevant information available.

5.6.2. Human information

No relevant information available.

5.6.3. Summary and discussion of repeated dose toxicity

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

Key Information:

In an OECD Test Guideline 407 study, to GLP, rats were administered diammonium hexachloropalladate by gavage for 28 days. The systemic NOAEL was the highest tested dose (100 mg/kg bw/day). Although there were some treatment-related effects at this dose (histological inflammation of the glandular stomach mucosa of both sexes and elevated mean white blood cell counts in males), these were considered to reflect a local irritant effect of the test substance rather than systemic toxicity (Matting, 2015). The critical oral NOAEL for diammonium hexachloropalladate (100 mg/kg bw/day) equates to an NOAEL of 30 mg/kg bw/day for palladium (based on MWt ratio).

In an GLP OECD Test Guideline 421 reproductive/developmental toxicity screening study (Török-Bathó, 2015), high dose (100 mg/kg bw/day) parental animals displayed only local effects in the glandular stomach mucosa, similar to those seen in the 28-day toxicity study.

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):
no adverse effect observed
(NOAEL: 100mg/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:

There are no data available in humans relating to repeated exposure to dipotassium (or diammonium) hexachloropalladate. However, a reliable 28-day oral gavage repeated dose toxicity and a reproduction/developmental screening toxicity study have been conducted with diammonium hexachloropalladate. Diammonium hexachloropalladate is considered to fall within the scope of the read-across category “hexachloropalladate salts”. See section 13 for full justification report.

In the first of these, the repeated dose toxicity of diammonium hexachloropalladate was assessed in a 28-day oral study on Wistar rats, conducted according to GLP and OECD Test Guideline 407 (Matting, 2015). Four groups of rats (containing five males and five females) were gavaged with diammonium hexachloropalladate via stomach tube at 0 (vehicle control, given corn oil), 10, 30 or 100 mg/kg bw/day. Rats were observed for signs of toxicity and mortality, and changes in body weight. Neurobehaviour was assessed (using a functional observation battery). On day 28, blood samples were collected for the analysis of haematological parameters and clinical chemistry. This was immediately followed by sacrifice and scheduled necropsy, in which a comprehensive range of organs and tissues were examined macroscopically and microscopically. Male animals of the high dose (100 mg/kg bw/day) group had multifocal dark red discolouration of the glandular stomach mucosa, with associated histological inflammatory changes of the gastric mucosa and a statistically significant elevation in mean white blood cell count. Similar inflammatory changes were evident histopathologically at a lower incidence in some females in the high dose group. These treatment-related effects in the high dose group were considered to reflect a local irritant effect of the test substance rather than systemic toxicity. Under the conditions of this study, the no-observed-adverse-effect level (NOAEL) for systemic toxicity was 100 mg/kg bw/day (the highest tested dose). The NOAEL for local effects was 30 mg/kg bw/day. The critical oral NOAEL for diammonium hexachloropalladate (100 mg/kg bw/day) equates to NOAELs of 30 and 112 mg/kg bw/day for palladium and dipotassium hexachloropalladate, respectively (based on MWt ratios).

In support, in a GLP OECD Test Guideline 421 reproductive/developmental toxicity screening study, rats were administered diammonium hexachloropalladate by gavage at up to 100 mg/kg bw/day for at least 28 days (Török-Bathó, 2015). The parental animals, in the high dose group, displayed similar local effects in the glandular stomach mucosa to those seen in the repeated dose toxicity study. However, no systemic effects were seen in the parental animals (resulting in a NOAEL of 100 mg/kg bw/day for systemic effects).

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. The compound is not expected to reach the lungs in appreciable quantities (based on respiratory tract deposition modelling data). Thus, inhalation will not be a significant route of exposure. Similarly, skin contact during production and/or use is expected to be negligible. As the oral route of exposure is considered the most appropriate, repeated dose toxicity studies were not carried out for the dermal or inhalation routes.

Justification for selection of repeated dose toxicity via oral route - systemic effects endpoint:
Reliable repeated dose toxicity GLP study, conducted according to OECD guidelines.

Justification for classification or non classification:

No adverse systemic effects were seen in reliable guideline studies (28-day oral repeated dose and a reproductive/developmental screening assay) with diammonium hexachloropalladate. The local irritant response is not considered relevant for classification as STOT-RE. As such, the results of these studies indicate that classification of diammonium hexachloropalladate or dipotassium hexachloropalladate 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 5.6. 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, TA 100 and TA 102 (main study (Experiments 1 and 2)) (with and without met. act.) S. typhimurium TA 98, TA 100 and TA 102 (range-finding study) (with and without met. act.) Test concentrations: Range-finding experiment: 0, 0.11, 0.35, 1.1, 3.5, 11.0, 34.8 or 110.0 µg/plate Main study: Experiment 1: 0, 0.11, 0.35, 1.1, 3.5, 11.0, 34.8 or 110.0 µg/plate Experiment 2: 0, 1.7, 3.4, 6.9, 13.8, 27.5, 55.0 or 110.0 µg/plate Positive control substance(s): 2-nitrofluorene	Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity - from 34.79 and/or 110 µg/plate in all strains, with and without S-9 vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity - from 55 and/or 110 µg/plate in all strains, with and without S-9	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9, Form: solid - liquid: suspension (full information in **Annex II**). **Reference** **Mc Garry S 2014**

Positive control substance(s): benzo(a)pyrene Positive control substance(s): sodium azide Positive control substance(s): 9-aminoacridine Positive control substance(s): mitomycin C Positive control substance(s): 2-aminoanthracene according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'. Remarks: Experiment 1	
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, TA 100 and TA 102 (main study (Experiments 1 and 2)) (with and without met. act.) S. typhimurium TA 98, TA 100 and TA 102 (range-finding study) (with and without met. act.) Test concentrations: Range-finding experiment: 0, 0.11, 0.35, 1.1, 3.5, 11.0, 34.8 or 110.0 µg/plate Main study: Experiment 1: 0, 0.11, 0.35, 1.1, 3.5, 11.0, 34.8 or 110.0 µg/plate Experiment 2: 0, 1.7, 3.4, 6.9, 13.8, 27.5, 55.0 or 110.0 µg/plate Positive control substance(s): 2-nitrofluorene Positive control substance(s): benzo(a)pyrene Positive control substance(s): sodium azide Positive control substance(s): 9-aminoacridine Positive control substance(s): mitomycin C Positive control substance(s): 2-aminoanthracene according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity - from 34.79 and/or 110 µg/plate in all strains, with and without S-9 vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity - from 55 and/or 110 µg/plate in all strains, with and without S-9 vehicle controls valid: valid negative controls valid: not examined positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'. Remarks: Experiment 1	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloropalladate, (full information in **Annex II**). **Reference** **Mc Garry S 2014**
Justification for type of information: Diammonium and dipotassium hexachloropalladate are considered to fall within the scope of the read-across category "hexachloropalladate salts". See section 13 for full justification report.		
mammalian cell gene mutation assay [gene mutation] (in vitro gene mutation study in mammalian cells - Type of	Test results: negative for mouse lymphoma L5178Y cells [mammalian cell line];	1 (reliable without restriction) key study

genotoxicity: gene mutation) mouse lymphoma L5178Y cells [mammalian cell line] (with and without met. act.) Test concentrations: In the range-finder, with and without S9: 0.3438, 0.6875, 1.375, 2.75, 5.50, 11.0 ug/ml In experiment 1: 2, 4, 6, 8, 10, 11 ug/ml In experiment 2: 1.5, 3, 4.5, 6, 7.5, 9, 11 ug/ml Positive control substance(s): 4-nitroquinoline-N-oxide ; benzo(a)pyrene according to OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) [in vitro gene mutation study in mammalian cells]	met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: valid positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	experimental study **Test material** diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9, Form: solid: crystalline (full information in **Annex II**). **Reference** **Lloyd M 2014**
mammalian cell gene mutation assay [gene mutation] (in vitro gene mutation study in mammalian cells - Type of genotoxicity: gene mutation) mouse lymphoma L5178Y cells [mammalian cell line] (with and without met. act.) Test concentrations: In the range-finder, with and without S9: 0.3438, 0.6875, 1.375, 2.75, 5.50, 11.0 ug/ml In experiment 1: 2, 4, 6, 8, 10, 11 ug/ml In experiment 2: 1.5, 3, 4.5, 6, 7.5, 9, 11 ug/ml Positive control substance(s): 4-nitroquinoline-N-oxide ; benzo(a)pyrene according to OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) [in vitro gene mutation study in mammalian cells]	Test results: negative for mouse lymphoma L5178Y cells [mammalian cell line]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: valid positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloropalladate, (full information in **Annex II**). **Reference** **Lloyd M 2014**
Justification for type of information: Diammonium and dipotassium hexachloropalladate are considered to fall within the scope of the read-across category "hexachloropalladate salts". See section 13 for full justification report.		
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study) lymphocytes: [primary culture] (with and without met. act.) Test concentrations: Range-finding study: 0 or ~0.04-11 µg/ml Main study: 0 or 2-11 µg/ml Positive control substance(s): mitomycin C Positive control substance(s): cyclophosphamide Positive control substance(s):	Test results: negative for lymphocytes: [primary culture]; met. act.: with and without genotoxicity: negative cytotoxicity: no cytotoxicity - no cultures were excluded from analysis based on cytotoxicity. The highest levels of cytotoxicity seen in the main study were for the 24-hr continuous treatment (without S-9), which saw 7, 7 and 9% at 8, 10 and 11 µg/ml, respectively vehicle controls valid: valid negative controls valid: valid positive controls valid: valid	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9; dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6, Form: solid - liquid:

vinblastine according to OECD Guideline 487 (In vitro Mammalian Cell Micronucleus Test)	Remarks: all strains/cell types tested - Migrated from field 'Test system'.	suspension (full information in **Annex II**). **Reference** **Lloyd M 2014**
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study) lymphocytes: [primary culture] (with and without met. act.) Test concentrations: Range-finding study: 0 or ~0.04-11 µg/ml Main study: 0 or 2-11 µg/ml Positive control substance(s): mitomycin C Positive control substance(s): cyclophosphamide Positive control substance(s): vinblastine according to OECD Guideline 487 (In vitro Mammalian Cell Micronucleus Test)	Test results: negative for lymphocytes: [primary culture]; met. act.: with and without genotoxicity: negative cytotoxicity: no cytotoxicity - no cultures were excluded from analysis based on cytotoxicity. The highest levels of cytotoxicity seen in the main study were for the 24-hr continuous treatment (without S-9), which saw 7, 7 and 9% at 8, 10 and 11 µg/ml, respectively vehicle controls valid: valid negative controls valid: valid positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloropalladate, (full information in **Annex II**). **Reference** **Lloyd M 2014**
Justification for type of information: Diammonium and dipotassium hexachloropalladate are considered to fall within the scope of the read-across category "hexachloropalladate salts". See section 13 for full justification report.		
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium, other: TA97a, TA98, TA100 and TA102 [bacteria] (with and without met. act.) Test concentrations: The test substance was dissolved in distilled water and diluted to 5-500 ug/plate [or possibly 10, 50, 100 or 500 ug/plate] in all four tester strains, in the absence or presence of (4% and 10 %) S9. The number of revertant colonies on the plates were recorded after 48 hours of incubation in the dark at 37degC. Positive control substance(s): methylmethanesulfonate Positive control substance(s): 2-aminofluorene according to Revised test protocol of Maron and Ames (1983) ; equivalent or similar to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	Test results: negative for S. typhimurium, other: TA97a, TA98, TA100 and TA102 [bacteria]; met. act.: with genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid: Test results: negative for S. typhimurium, other: TA97a, TA98, TA100 and TA102 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: positive controls valid:	2 (reliable with restrictions) supporting study experimental study **Test material** Dipotassiumhexachloropalladate; dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6, (full information in **Annex II**). **Reference** **Bunger J. et al. 1996**
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro	Test results:	2 (reliable with restrictions)

gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium TA 98 [bacteria] (without met. act.) S. typhimurium TA 100 [bacteria] (without met. act.) Test concentrations: The test substance was dissolved in distilled water and introduced onto a dish with the test culture in doses of 0.1, 1, 10, 100 or 1000 µg/plate, in the absence of a mammalian metabolic activation system. Positive control substance(s): no guideline followed Ability to induce mutations in Salmonella typhimurium strains. Limited Ames test.	negative for S. typhimurium TA 98 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: not specified vehicle controls valid: not specified negative controls valid: not specified positive controls valid: not specified Test results: negative for S. typhimurium TA 100 [bacteria]; met. act.: without genotoxicity: negative cytotoxicity: not specified vehicle controls valid: not specified negative controls valid: not specified positive controls valid: not specified	supporting study experimental study **Test material** dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6, Form: not specified (full information in **Annex II**). **Reference** **Suraikina T.I. et al. 1979**

5.7.1.2. In vivo data

No relevant information available.

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):

Dipotassium hexachloropalladate was not mutagenic in a bacterial reverse mutation (Ames) assay using four Salmonella typhimurium strains (TA97a, TA98, TA100 and TA102), when tested at up to cytotoxic concentrations in the presence and absence of a rat liver metabolic activation (S9) system (Bunger et al., 1996). In an in vitro mouse lymphoma assay, conducted according to GLP and OECD Test Guideline 476, diammonium hexachloropalladate failed to induce mutations when tested up to the limit of solubility (11 µg/ml) in the presence and absence of S9 (Lloyd, 2014a). In an in vitro mammalian cell micronucleus test, conducted according to GLP and OECD Test Guideline 487, diammonium hexachloropalladate at up to the limit of solubility (11 µg/ml) did not cause a treatment-related increase in the frequency of micronuclei in cultured human lymphocytes, with or without S9 (Lloyd, 2014b).

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

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

No in vivo data were identified.

Value used for CSA (genetic toxicity in vivo): Genetic toxicity: no study available

Justification for classification or non classification

No evidence of genotoxic activity has been seen in reliable in vitro assays in somatic cells, including GLP guideline studies assessing mutagenic and clastogenic activity. No studies specifically assessing the mutagenic activity in germ cells were identified. However, no effects on reproductive parameters were seen in the reproductive/developmental toxicity screening assay. As such, classification of diammonium hexachloropalladate or dipotassium hexachloropalladate for germ cell mutagenicity is not warranted, according

to EU CLP criteria (EC 1272/2008).

Additional information:

No studies conducted in humans were identified (although in vitro studies using human lymphocytes are described below).

Dipotassium hexachloropalladate was assessed for mutagenic activity in a bacterial reverse mutation (Ames) assay, similar to OECD Test Guideline 471, using Salmonella typhimurium strains TA97a, TA98, TA100 and TA102 and tested in the presence and absence of a rat liver metabolic activation (S9) system. (The recommended strain TA1535 was omitted.) No mutagenic effect was seen in any of the four strains at up to cytotoxic concentrations, either in the presence or absence of S9 (Bunger et al., 1996). In support, in a limited Ames test, dipotassium hexachloropalladate was not mutagenic in two strains of S. typhimurium (TA98 and TA100) when tested at up to 1 mg/plate, in the absence of metabolic activation (Suraikina et al., 1979).

As there are some limitations in the existing bacterial mutagenicity database for dipotassium hexachloropalladate (i.e. the recommended strain TA1535 was not tested), it was prudent to also consider the closely-related substance diammonium hexachloropalladate, which has recently been assessed for mutagenicity in a bacterial reverse mutation (Ames) assay performed to GLP, and according to OECD Test Guideline 471. Triplicate cultures of Salmonella typhimurium strains TA98, TA100, TA102, TA1535 and TA1537 were tested with and without the addition of rat liver S9, in two separate experiments. In the first experiment, agar containing the test substance at up to 110 µg/plate was incubated with the bacterial strains for 3 days. The second experiment, also using concentrations of up to 110 µg/plate, included an additional 20-minute pre-incubation step for cultures treated in the presence of S9. No evidence of mutagenicity was observed in any experiment. Cytotoxicity was observed from 34.79 and/or 110 µg/plate in all strains, with and without S9. In the second experiment, cytotoxicity was seen from 55 and/or 110 µg/plate. Vehicle and positive controls performed as expected. Under the conditions of this assay, diammonium hexachloropalladate was not mutagenic (Mc Garry, 2014).

No studies investigating the genotoxicity of dipotassium hexachloropalladate in mammalian systems were identified. However, diammonium hexachloropalladate was tested for its ability to induce mutations at the hprt locus in an in vitro mouse lymphoma assay conducted in accordance with OECD Test Guideline 476 and to GLP. It was tested in mouse lymphoma (L5178Y) cells at multiple concentrations up to the limit of solubility (11 µg/ml) in the presence and absence of rat liver (S9) metabolic activation. There was a minor increase in mutant frequency at a single low concentration in one of the two duplicate experiments that was within the acceptable range for vehicle controls, and was not considered biologically relevant. There were no other statistically significant increases in mutations, and no linear trend was observed. In conclusion, the test material was considered non-mutagenic to mouse lymphoma cells in vitro under the conditions of this assay (Lloyd, 2014a).

Further, diammonium hexachloropalladate has been investigated in a reliable in vitro micronucleus test, conducted to GLP and according to OECD Test Guideline 487. Following a range-finding study, whole blood was obtained from two healthy male volunteers. Blood was treated with the test substance (in dimethylformamide) at up to the limit of solubility (11 µg/ml), with or without rat liver S9. Treatment was either continuous (24 hours, without S9 only), or for 3 hours, followed by a 21-hour recovery phase (with and without S9). The only statistically significant increased frequency of micronucleated lymphocytes was seen for cultures treated with 8 µg/ml for 24 hours without S9. As other cultures at this - and higher concentrations - demonstrated no such effect, this was not considered biologically relevant. Positive and negative controls performed as expected. Under the conditions of this assay, diammonium hexachloropalladate displayed no significant evidence of genotoxicity in human lymphocytes, with or without the addition of S9 (Lloyd, 2014b).

Diammonium hexachloropalladate is considered to fall within the scope of the read-across category “hexachloropalladate salts”. See section 13 for full justification report.

Justification for selection of genetic toxicity endpoint
GLP study, conducted according to OECD guidelines.

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 5.7. Studies on fertility

Method	Results	Remarks
rat (Wistar [rat]) male/female screening for reproductive / developmental toxicity - based on test type (migrated information) oral: gavage Doses / Concentrations: 0 Basis: other: nominal: gavage Doses / Concentrations: 10 mg/kg bw/day Basis: other: nominal: gavage Doses / Concentrations: 30 mg/kg bw/day Basis: other: nominal: gavage Doses / Concentrations: 100 mg/kg	**First parental generation (P0)** NOAEL - fertility/reproductive parameters (PO) 100 mg/kg bw/day (nominal)) (male/female) based on: reproductive function (sperm measures) [reproductive toxicity] ; reproductive performance [reproductive toxicity] NOAEL - systemic toxicity (PO) 100 mg/kg bw/day (nominal)) (male/female) based on: No systemic toxicity was observed. Treatment related effects in the high dose group were considered to reflect a local irritant effect	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9, Form: solid: particulate/powder - migrated information: powder (full information in

bw/day Basis: other: nominal: gavage Vehicle: corn oil Exposure: Males were dosed for 28 days (14 days pre-mating and 14 days mating/post-mating). They were then euthanized and subjected to necropsy examination. Females were dosed for 14 days pre-mating, for up to 4 days mating period, through gestation and up to and including the day before necropsy (at least 4 days post-partum dosing). The day of birth (i.e. when parturition was complete) was defined as Day 0 post-partum. (The test item was administered daily by oral gavage on a 7 days/week basis.) according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	of the test substance rather than systemic toxicity. NOAEL - local effects (PO) 30 mg/kg bw/day (nominal)) (male/female) based on: see 'Remark' - Test item-related macroscopic and microscopic findings were noted in the glandular stomach mucosa at the top dose (100 mg/kg bw/day). The changes were characterized as red cytoplasmic glandular foreign material, mixed cellular diffuse inflammation of glandular mucosa with/without submucosal lymphoid follicle formation, erosion or ulcer of the glandular mucosa (mainly fundic and pyloric). These lesions were in correlation with macroscopic findings seen at necropsy, and are considered a treatment-related local effect. **F1 generation** NOAEL : 100 mg/kg bw/day (nominal) (male/female) based on: clinical signs ; mortality ; body weight and weight gain ; gross pathology **Overall reproductive toxicity** not specified Lowest effective dose / concentration Relation to other toxic effects:	**Annex II**). **Reference** **Török-Bathó, M 2015**
rat (Wistar [rat]) male/female screening for reproductive / developmental toxicity - based on test type (migrated information) oral: gavage Doses / Concentrations: 0 Basis: other: nominal: gavage Doses / Concentrations: 10 mg/kg bw/day Basis: other: nominal: gavage Doses / Concentrations: 30 mg/kg bw/day Basis: other: nominal: gavage Doses / Concentrations: 100 mg/kg bw/day Basis: other: nominal: gavage Vehicle: corn oil Exposure: Males were dosed for 28 days (14 days pre-mating and 14 days mating/post-mating). They were then euthanized and subjected to necropsy examination. Females were dosed for 14 days pre-mating, for up to 4 days mating period, through gestation and up to and including the day before necropsy (at least 4 days post-partum dosing). The day of birth (i.e. when parturition was complete) was defined as Day 0 post-partum. (The test item was administered daily by oral	**First parental generation (P0)** NOAEL - fertility/reproductive parameters (PO) 100 mg/kg bw/day (nominal)) (male/female) based on: reproductive function (sperm measures) [reproductive toxicity] ; reproductive performance [reproductive toxicity] NOAEL - systemic toxicity (PO) 100 mg/kg bw/day (nominal)) (male/female) based on: No systemic toxicity was observed. Treatment related effects in the high dose group were considered to reflect a local irritant effect of the test substance rather than systemic toxicity. NOAEL - local effects (PO) 30 mg/kg bw/day (nominal)) (male/female) based on: see 'Remark' - Test item-related macroscopic and microscopic findings were noted in the glandular stomach mucosa at the top dose (100 mg/kg bw/day). The changes were characterized as red cytoplasmic glandular foreign material, mixed cellular diffuse inflammation of glandular mucosa with/without	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloropalladate, (full information in **Annex II**). **Reference** **Török-Bathó, M 2015**

gavage on a 7 days/week basis.) according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	submucosal lymphoid follicle formation, erosion or ulcer of the glandular mucosa (mainly fundic and pyloric). These lesions were in correlation with macroscopic findings seen at necropsy, and are considered a treatment-related local effect. **F1 generation** NOAEL : 100 mg/kg bw/day (nominal) (male/female) based on: clinical signs ; mortality ; body weight and weight gain ; gross pathology **Overall reproductive toxicity** not specified Lowest effective dose / concentration Relation to other toxic effects:	
Justification for type of information: Diammonium and dipotassium hexachloropalladate are considered to fall within the scope of the read-across category “hexachloropalladate salts”. See section 13 for full justification report.		

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

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

Table 5.8. Studies on developmental toxicity

Method	Results	Remarks
rat (Wistar [rat]) oral: gavage Vehicle: corn oil Exposure: Males were dosed for 28 days (14 days pre-mating and 14 days mating/post-mating). They were then euthanized and subjected to necropsy examination. Females were dosed for 14 days pre-mating, for up to 4 days mating period, through gestation and up to and including the day before necropsy (at least 4 days post-partum dosing). The day of birth (i.e. when parturition was complete) was defined as Day 0 post-partum. (The test item was administered daily by oral gavage on a 7 days/week basis.) according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	**Maternal animals:** NOAEL: 100 mg/kg bw/day (nominal) based on: (test mat.) **Fetuses:** Fetal abnormalities not specified NOAEL: 100 mg/kg bw/day (nominal) based on: (test mat.) **Overall developmental toxicity:** no Lowest effective dose / concentration: Relation to maternal toxicity:	1 (reliable without restriction) key study experimental study **Test material** diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Török-Bathó, M**

		2015
rat (Wistar [rat]) oral: gavage Vehicle: corn oil Exposure: Males were dosed for 28 days (14 days pre-mating and 14 days mating/post-mating). They were then euthanized and subjected to necropsy examination. Females were dosed for 14 days pre-mating, for up to 4 days mating period, through gestation and up to and including the day before necropsy (at least 4 days post-partum dosing). The day of birth (i.e. when parturition was complete) was defined as Day 0 post-partum. (The test item was administered daily by oral gavage on a 7 days/week basis.) according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	**Maternal animals:** NOAEL: 100 mg/kg bw/day (nominal) based on: (test mat.) **Fetuses:** Fetal abnormalities not specified NOAEL: 100 mg/kg bw/day (nominal) based on: (test mat.) **Overall developmental toxicity:** no Lowest effective dose / concentration: Relation to maternal toxicity:	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Dipotassium hexachloropalladate, (full information in **Annex II**). **Reference** **Török-Bathó, M 2015**
Justification for type of information: Diammonium and dipotassium hexachloropalladate are considered to fall within the scope of the read-across category “hexachloropalladate salts”. See section 13 for full justification report.		

5.9.2.2. Human information

No relevant information available.

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

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

In an OECD Test Guideline 421 reproduction and developmental toxicity screening study, to GLP, parental (F0) rats (12/sex/group) were administered diammonium hexachloropalladate by gavage at 0 (corn oil), 10, 30 or 100 mg/kg bw/day. No adverse effects on reproductive parameters of parent males and females (F0 animals), or on developmental of offspring (FI generation), were observed at any dose, resulting in a NOAEL of 100 mg/kg bw/day for such effects (Török-Bathó, 2015).

Diammonium hexachloropalladate is closely related to dipotassium hexachloropalladate and considered a suitable surrogate for read-across for this endpoint.

Value used for CSA (route: oral):
no adverse effect observed (NOAEL): 100mg/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:

There are no data available in humans relating to the potential reproductive effects of dipotassium (or diammonium) hexachloropalladate. However, a reliable reproduction/developmental screening toxicity study has been conducted with diammonium hexachloropalladate. Diammonium hexachloropalladate is considered to fall within the scope of the read-across category “hexachloropalladate salts”. See section 13 for full justification report.

The potential of diammonium hexachloropalladate to adversely affect the fertility and reproductive parameters of rats was investigated in a reproductive and developmental screening study conducted according to OECD Test Guideline 421 and to GLP. The test material (in corn oil) was administered by oral gavage. Males were dosed for 28 days (14 days pre-mating and 14 days mating/post-mating). Females were dosed for 14 days pre-mating, for up to 4 days mating period, through gestation and up to and including the day before necropsy (at least 4 days post-partum dosing).

Three dose groups (10, 30 and 100 mg/kg bw/day) and a vehicle control group were used, each containing 12 males and 12 females (F0 animals). F0 animals were observed for clinical signs of toxicity throughout the study, with body weights and food consumption monitored. At necropsy, animals were subjected to external and internal macroscopic examinations for any abnormalities or pathological changes. Special attention was paid to the reproductive organs. The numbers of implantation sites and corpora lutea were recorded. Histopathological examination was performed on the ovaries, testes and epididymides of all animals in the control and high-dose groups, with special emphasis on the qualitative stages of spermatogenesis and histopathology of interstitial testicular structure. A number of reproductive indices were calculated from the collected data.

Test item-related macroscopic and microscopic findings were noted in parental animals in the glandular stomach mucosa at a dose level of 100 mg/kg bw/day (resulting in a NOAEL of 30 mg/kg bw/day for local effects). No test item-related microscopic changes were noted in the reproductive organs at any dose level. There was no impact on fertility or on the measured reproductive parameters at any dose level. The NOAEL for reproductive toxicity was 100 mg/kg bw/day, the highest dose tested (Török-Bathó, 2015).

Justification for selection of Effect on fertility via oral route:
Reliable GLP study, conducted according to OECD guidelines, and the only reproduction/developmental toxicity study available.

Developmental toxicity

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

In an OECD Test Guideline 421 reproduction and developmental toxicity screening study, to GLP, parental (F0) rats (12/sex/group) were administered diammonium hexachloropalladate by gavage at 0 (corn oil), 10, 30 or 100 mg/kg bw/day. No adverse effects on reproductive parameters of parental (F0) animals, or on development of offspring (FI generation), were observed at any dose, resulting in a NOAEL of 100 mg/kg bw/day for such effects (Török-Bathó, 2015).

Diammonium hexachloropalladate is closely related to dipotassium hexachloropalladate and considered a suitable surrogate for read-across for this endpoint.

Value used for CSA (route: oral):
no adverse effect observed (NOAEL): 100mg/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:

There are no data available in humans relating to the potential developmental effects of dipotassium (or diammonium) hexachloropalladate. However, a reliable reproduction/developmental screening toxicity study has been conducted with diammonium hexachloropalladate. Diammonium hexachloropalladate is considered to fall within the scope of the read-across category “hexachloropalladate salts”. See section 13 for full justification report.

The potential of diammonium hexachloropalladate to adversely affect the development of rats was investigated in a guideline reproductive and developmental screening study conducted according to OECD Test Guideline 421 and to GLP. The test material (in corn oil) was administered by oral gavage. Males were dosed for 28 days (14 days pre-mating and 14 days mating/post mating). Females were dosed for 14 days pre-mating, for up to 4 days mating period, through gestation and up to and including the day before necropsy (at least 4 days post-partum dosing). Three dose groups (10, 30 and 100 mg/kg bw/day) and a vehicle control group were used, each containing 12 males and 12 females.

Parental (F0) animals were observed for clinical signs of toxicity throughout the study, with body weights and food consumption monitored. At necropsy, animals were subjected to external and internal macroscopic examinations for any abnormalities or pathological changes. Special attention was paid to the reproductive organs. Pups were carefully examined for gross abnormalities at necropsy (on postnatal day 4).

Macroscopic and microscopic findings were noted in parental animals in the glandular stomach mucosa at a dose level of 100 mg/kg bw/day, reflecting a treatment-related local effect. No systemic toxicity was observed in the F0 animals. There was no developmental toxicity effect at any dose level. Consequently, the NOAEL for developmental toxicity was 100 mg/kg bw/day, the highest dose tested (Török-Bathó, 2015).

Justification for selection of Effect on developmental toxicity: via oral route:
Reliable GLP study, conducted according to OECD guidelines, and the only reproduction/developmental toxicity study available.

Justification for classification or non classification:

No adverse effects on reproductive parameters (sexual function or fertility) or development of offspring were seen in a reliable guideline screening assay with diammonium hexachloropalladate. As such, classification of diammonium or dipotassium hexachloropalladate 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 5.9. Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type
Acute toxicity	oral	adverse effect observed (LD50): 1448mg/kg bw
Acute toxicity	dermal	no study available
Acute toxicity	inhalation	no study available
Irritation / Corrosivity	skin	adverse effect observed (irritating)
Irritation / Corrosivity	eye	adverse effect observed (irreversible damage)
Irritation / Corrosivity	resp. tract	no study available
Sensitisation	skin	adverse effect observed (sensitising)
Sensitisation	resp. tract	no study available
Repeated dose toxicity	oral	no adverse effect observed (NOAEL): 100mg/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: no adverse effect observed (negative) In vivo: no study available
Reproductive toxicity: effects on fertility	oral	no adverse effect observed (NOAEL): 100mg/kg bw/day (subacute; rat [common rodent species])
Reproductive toxicity: effects on fertility	dermal	no study available
Reproductive toxicity: effects on fertility	inhalation	no study available
Reproductive toxicity: developmental toxicity	oral	no adverse effect observed (NOAEL): 100mg/kg bw/day (subacute; rat [common rodent species])
Reproductive toxicity: developmental toxicity	dermal	no study available
Reproductive toxicity: developmental toxicity	inhalation	no study available

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

Table 5.10. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 5.27mg/m³	repeated dose toxicity (Oral)
Inhalation	Systemic effects - Acute	no hazard identified	
Inhalation	Local effects - Long-term	medium hazard (no threshold derived)	sensitisation (skin)
Inhalation	Local effects - Acute	medium hazard (no threshold derived)	sensitisation (skin)
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level) 1.49mg/kg bw/day	repeated dose toxicity (Oral)
Dermal	Systemic effects - Acute	no hazard identified	
Dermal	Local effects - Long-term	medium hazard (no threshold derived)	sensitisation (skin)

Dermal	Local effects - Acute	medium hazard (no threshold derived)	sensitisation (skin)
Eyes	Local effects	medium hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Modified dose descriptor starting point: NOAEC

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; Systemic NOAEL from a well-conducted 28-day gavage study; the highest dose was set at 100 mg/kg bw/day on the basis of a 14-day dose range finding study (doses of 300 and 600 mg/kg bw/day were considered to be higher than the maximum tolerated dose))

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. Read-across from the structurally-similar compound, diammonium hexachloropalladate was used to fill the reproductive/ developmental and repeated dose toxicity (oral) endpoints. No AF is considered necessary for the use of read-across in this instance since the source substance displays a very high degree of similarity to the target compound. Notably, the counter ions (ammonium or potassium) are not anticipated to differentially influence the toxicity of the palladium (II) species. Moreover, the DNEL was derived on the basis of palladium itself)

AF for remaining uncertainties: 1 (Not required)

Further explanation on hazard conclusions:

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

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

See discussion section (Hazard via inhalation route: systemic effects following acute exposure)

Inhalation Local effects - Long-term

Further explanation on hazard conclusions:

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

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

See discussion section (Hazard via inhalation route: local effects following acute exposure)

Dermal Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Modified dose descriptor starting point: NOAEL

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; Systemic NOAEL from a well-conducted 28-day gavage study; the highest dose was set at 100 mg/kg bw/day on the basis of a 14-day dose range finding study (doses of 300 and 600 mg/kg bw/day were considered to be higher than the maximum tolerated dose))

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 (The default ECHA AF of 4 for rat for toxicokinetic differences in metabolic rate (allometric scaling) is considered unnecessary as the compound is inorganic and is consequently not metabolised 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", while systemically available palladium is excreted predominantly via the biliary/faecal route)

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. Read-across from the structurally-similar compound, diammonium hexachloropalladate was used to fill the reproductive/ developmental and repeated dose toxicity (oral) endpoints. No AF is considered necessary for the use of read-across in this instance since the source substance displays a very high degree of similarity to the target compound. Notably, the counter ions (ammonium or potassium) are not anticipated to differentially influence the toxicity of the palladium (II) species. Moreover, the DNEL was derived on the basis of palladium itself)

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

Further explanation on hazard conclusions:

See discussion section (Hazard via dermal route: systemic effects following acute exposure)

Dermal Local effects - Long-term

Further explanation on hazard conclusions:

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

Dermal Local effects - Acute

Further explanation on hazard conclusions:

See discussion section (Hazard via dermal route: local effects following acute exposure)

Discussion:

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

Justification for route to route extrapolation

As no relevant data on effects of repeated exposure to dipotassium hexachloropalladate in humans or laboratory animals are available, route-to-route extrapolation to calculate an inhalation DNEL from a reliable repeated dose oral toxicity study on a member of the "hexachloropalladate salts" category (diammonium hexachloropalladate) was considered a suitable alternative (particularly as first pass effects are not expected to be significant for an inorganic compound).

The oral NOAEL for diammonium hexachloropalladate was 100 mg/kg bw/day. This equates to NOAELs of 30 and 112 mg/kg bw/day for palladium and dipotassium hexachloropalladate, respectively (based on MWt ratios).

In the absence of data allowing quantitative comparison between the extent of absorption following inhalation and oral exposure, this derivation utilises the REACH guidance default assumption that the absorption percentage for the oral route is half that of the inhalation route, and a default factor of 2 is proposed for absorption differences in the case of oral-to-inhalation extrapolation.

Corrected inhalatory NOAEC (worker, 8 h exposure/day) = oral NOAEL*(1/sRv[rat])*(ABS[oral-rat]/ABS[inh-human]) *(sRV[human]/wRV)

= 112 mg/kg bw/day*(1/0.38 m3/kg bw/day)*(1/2)*(6.7 m3 [8h]/10 m3 [8h]) = 98.7 mg/m3

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

It is therefore 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 = 88.2*4 = 395 mg/m3.

Justification and comments

In a guideline (OECD TG 407) 28-day gavage toxicity study in rats, on the closely-related read-across compound diammonium hexachloropalladate, the systemic NOAEL was the highest tested dose (100 mg/kg bw/day). Although there were some treatment-related effects at this dose (histological inflammation of the glandular stomach mucosa of both sexes and elevated mean white blood cell counts in males), these were considered to reflect a local irritant effect of the test substance rather than systemic toxicity (Matting, 2015).

In another guideline study (OECD TG 421), parental animals displayed similar effects in the glandular stomach mucosa as those seen in the 28-day toxicity study at the top tested dose (100 mg/kg bw/day), although no systemic effects were seen in the parenteral animals at this dose (Török-Bathó, 2015).

Further,no reproductive/developmental toxicity was observed in this study(Török-Bathó, 2015) following gavage dosing of rats at the highest tested dose (100 mg/kg bw/day of diammonium hexachloropalladate). The possible limitations of this study, as reassurance of an absence of reproductive effects, are acknowledged. ECHA (2012a) guidance recommends “application of an additional assessment factor of 2 to 5, decided on a case-by-case basis that should account for the limitations of this study”. Even applying the most conservative of these (i.e. an additional AF of 5) results in a DNEL higher than that derived for repeated dose effects (as the AF of 6 for differences in duration of exposure would not also be required).

Hence, the systemic NOAEL of 100 mg/kg bw/day (equivalent to 30 and 112 mg/kg bw/day for palladium and dipotassium hexachloropalladate, respectively) from the repeated dose study on diammonium hexachloropalladate was taken as the critical point of departure for calculating the long-term systemic DNELs for dipotassium hexachloropalladate, and is considered protective of fertility and developmental toxicity.

The DNEL (5.27 mg/m3) equates to a palladium exposure of 1.41 mg/m3.

Hazard via inhalation route: systemic effects following acute exposure

Justification and comments

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

There are no data in relation to acute inhalation exposure to dipotassium hexachloropalladate. In a guideline (OECD TG 401) acute oral toxicity study in rats, an LD50 value of 1448 mg/kg bw (males and females combined) was obtained (Zechel, 1990). The compound is classified in Category 4 for acute oral toxicity according to CLP criteria. An oral N(L)OAEL (for sub-lethal effects) could be modified into an inhalation N(L)OAEC using route-to-route extrapolation. However, ECHA (2012a) guidance on DNEL calculation notes

that this “procedure introduces significant uncertainties especially in relation to what inhalation time-frame this extrapolated N(L)OAEC would represent, and the procedure is therefore discouraged”.

ECHA (2015a,b) guidance on requirements for acute toxicity testing notes that “inhalable particles…are generally smaller than 100 µm in diameter. Particles larger than 100 µm are less likely to be inhalable”. In non-guideline granulometry screening tests, the average 10th, 50th and 90th percentile average particle sizes for dipotassium hexachloropalladate were 15.0, 34.4 and 56.8 µm, respectively, and the average mean particle size was 35.16 µm (CILAS, 2008a,b). Further, dustiness testing with dipotassium hexachloropalladate returned a mass median aerodynamic diameter (MMAD) value of 25.7 µm (Parr, 2011; Selck and Parr, 2011), indicating that a significant proportion of the substance is likely to be inhalable. However, respiratory tract deposition modelling with the dustiness data yielded output values of 52.5, 0.17 and 0.15% for the head, TB and pulmonary regions of the respiratory tract, respectively. Hence, very little airborne substance (<1%) will be deposited in the lower regions of the human respiratory tract, i.e. the TB or pulmonary regions via oronasal normal augmenter breathing. Most of the inhaled fraction is likely to be retained in the head region and therefore would be cleared by ingestion, along with that deposited in the TB region, and oral bioavailability will again predominantly determine systemic uptake. Less than 1% is capable of reaching the alveoli. Consequently, inhalation is not considered to be a significant route of exposure.

Further, given that the long-term systemic inhalation DNEL is relatively high (5.27 mg/m3), setting acute DNELs is unnecessary, based on the high-level principle referenced in ECHA (2012a). This criterion states that “As a rule of thumb, a DNELacute should be set for acutely toxic substances if actual peak exposure levels significantly exceed the long-term DNEL”. This is typically inferred to mean several fold exceedance for task-based (e.g. 15 minute TWA) situations. The foreseeable industrial situations are highly unlikely to result in airborne peak exposures well above 5.27 mg/m3as these would not be tolerated in the workplaces (due to the general standards applicable to control of particulates). Consequently, no worker-DNEL for acute systemic toxicity has been calculated.

“A qualitative risk characterisation for this endpoint could be performed for substances of very high or high acute toxicity classified in Category 1, 2 and 3 according to CLP…. when the data are not sufficiently robust to allow the derivation of a DNEL” (ECHA, 2012b). However, dipotassium hexachloropalladate is classified in Category 4 according to CLP, so a qualitative assessment is not required.

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

Justification and comments

There are no data in relation to respiratory tract irritation or sensitisation in humans or laboratory animals. Consequently, no worker-DNEL for respiratory tract irritation/corrosion or sensitisation has been calculated.

However, according to ECHA (2012b) guidance “since sensitisation is essentially systemic in nature, it is important for the purposes of risk management to acknowledge that skin sensitisation may be acquired by other routes of exposure than dermal. There is therefore a need for cautious use of known contact allergens in products to which consumers or workers may be exposed by inhalation”. Dipotassium hexachloropalladate is classified as a moderate skin sensitiser, on the basis of read-across from diammonium hexachloropalladate. Therefore, consider recommended Risk Management Measures/Operational Conditions (RMMs/OCs) in Table E.3-1 of ECHA (2012b).

Hazard via inhalation route: local effects following acute exposure

Justification and comments

There are no data in relation to respiratory tract irritation or sensitisation in humans or laboratory animals. Consequently, no worker-DNEL for acute local effects in the respiratory tract has been calculated.

However, according to ECHA (2012b) guidance, "since sensitisation is essentially systemic in nature, it is important for the purposes of risk management to acknowledge that skin sensitisation may be acquired by other routes of exposure than dermal. There is therefore a need for cautious use of known contact allergens in products to which consumers or workers may be exposed by inhalation". Dipotassium hexachloropalladate is classified as a moderate skin sensitiser, on the basis of read-across from diammonium hexachloropalladate. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

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

Justification for route to route extrapolation

As no relevant data on effects of repeated exposure to dipotassium hexachloropalladate in humans or laboratory animals are available, route-to-route extrapolation to calculate a dermal DNEL from a reliable repeated dose oral toxicity study on a member of the "hexachloropalladate salts" category (diammonium hexachloropalladate) was considered a suitable alternative (particularly as first pass effects are not expected to be significant for an inorganic compound).

The oral NOAEL for diammonium hexachloropalladate was 100 mg/kg bw/day. This equates to NOAELs of 30 and 112 mg/kg bw/day for palladium and dipotassium hexachloropalladate, respectively (based on MWt ratios).

Estimation of dermal absorption is based on relevant available information (mainly water solubility, molecular weight and log Pow) and expert judgement. Dipotassium hexachloropalladate, with a water solubility in excess of 3.41 g/L (Gregory, 2014), may be able to cross the lipid-rich environment of the stratum corneum to a "moderate to high" extent (ECHA, 2014). In the light of the limited available experimental data, ECHA guidance indicates that a default value of 100% dermal absorption should be used (ECHA, 2014). However, specific guidance on the health risk assessment of metals indicates that molecular weight and log Pow considerations 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 tentatively proposes dermal absorption figures: 1.0 and 0.1% following exposure to liquid/wet media and dry (dust) respectively (ICMM, 2007). Nevertheless, dipotassium hexachloropalladate is classified as a skin irritant. This is based on the observation of moderate skin irritation in rabbits (Zechel, 1989a). Such irritant potential may disrupt skin barrier function, facilitating dermal penetration. As such, it is considered health precautionary to take forward the ECHA default dermal absorption value of 100%.

In the absence of data allowing quantitative comparison between absorption following oral and dermal exposure, and noting that, in general, dermal absorption will not be higher than oral absorption, no default factor (i.e. factor of 1) is required for oral-to-dermal extrapolation (in line with ECHA (2012a) guidance).

Justification and comments

In a guideline (OECD TG 407) 28-day gavage toxicity study in rats, on the closely-related read-across compound diammonium hexachloropalladate, the systemic NOAEL was the highest tested dose (100 mg/kg bw/day). Although there were some treatment-related effects at this dose (histological inflammation of the glandular stomach mucosa of both sexes and elevated mean white blood cell counts in males), these were considered to reflect a local irritant effect of the test substance rather than systemic toxicity (Matting, 2015).

In another guideline study (OECD TG 421), parental animals displayed similar effects in the glandular stomach mucosa as those seen in the 28-day toxicity study at the top tested dose (100 mg/kg bw/day), although no systemic effects were seen in the parenteral animals at this dose (Török-Bathó, 2015).

Further,no reproductive/developmental toxicity was observed in this study(Török-Bathó, 2015) following gavage dosing of rats at the highest tested dose (100 mg/kg bw/day of diammonium hexachloropalladate).

The possible limitations of this study, as reassurance of an absence of reproductive effects, are acknowledged. ECHA (2012a) guidance recommends “application of an additional assessment factor of 2 to 5, decided on a case-by-case basis that should account for the limitations of this study”. Even applying the most conservative of these (i.e. an additional AF of 5) results in a DNEL higher than that derived for repeated dose effects (as the AF of 6 for differences in duration of exposure would not also be required).

Hence, the systemic NOAEL of 100 mg/kg bw/day (equivalent to 30 and 112 mg/kg bw/day for palladium and dipotassium hexachloropalladate, respectively) from the repeated dose study on diammonium hexachloropalladate was taken as the critical point of departure for calculating the long-term systemic DNELs for dipotassium hexachloropalladate, and is considered protective of fertility and developmental toxicity.

The DNEL (1.49 mg/kg bw/day) equates to a palladium exposure of 0.40 mg/kg bw/day.

Hazard via dermal route: systemic effects following acute exposure

Justification and comments

DNELs for acute toxicity should be calculated if an acute toxicity hazard, leading to classification and labelling (i.e. under EU CLP regulations) has been identified and there is a potential for high peak exposures (this is only usually relevant for inhalation exposures). No acute dermal toxicity study was conducted on dipotassium hexachloropalladate. In a guideline (OECD TG 401) acute oral toxicity study in rats, an LD50 value of 1448 mg/kg bw (males and females combined) was obtained for dipotassium hexachloropalladate (Zechel, 1990). The compound is classified in Category 4 for acute oral toxicity according to CLP criteria.

Skin contact to dipotassium hexachloropalladate during production and/or use is expected to be negligible. Given that the long-term systemic dermal DNEL is relatively high (1.49 mg/kg bw/day), setting acute DNELs is unnecessary, based on the high-level principle referenced in ECHA (2012a). This criterion states that “As a rule of thumb, a DNELacute should be set for acutely toxic substances if actual peak exposure levels significantly exceed the long-term DNEL”. As consumer exposure is expected to be negligible, such peak exposures are not anticipated. Consequently, no worker-DNEL for acute systemic dermal toxicity has been calculated.

"A qualitative risk characterisation for this endpoint could be performed for substances of very high or high acute toxicity classified in Category 1, 2 and 3 according to CLP…. when the data are not sufficiently robust to allow the derivation of a DNEL" (ECHA, 2012b). However, dipotassium hexachloropalladate is classified in Category 4 according to CLP, so a qualitative assessment is not required.

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

Justification and comments

In a guideline (OECD TG 404) skin irritation study in rabbits, dipotassium hexachloropalladate produced "slight to moderate" skin irritation (Zechel, 1989a). The compound is classified for skin irritation as Category 2 under CLP. Further, no dose-response data was available from which to derive a DNEL, therefore a qualitative assessment was considered appropriate. At worst this would be considered in the low hazard band according to ECHA (2012b) guidance.

In another guideline (OECD TG 429) study, the structurally-related compound diammonium hexachloropalladate induced sensitisation in the mouse local lymph node assay (LLNA). The calculated EC3 value was 11.9% (Valiczko, 2013). This compound is classified for skin sensitisation as Category 1B, under CLP. Accordingly, an identical classification was adopted for dipotassium hexachloropalladate.

According to ECHA (2012b) guidance "moderate skin sensitisers (classified in Sub-category 1B in CLP) are allocated to the moderate hazard category band on the basis that exposure to these moderate skin sensitising substances should be well-controlled".

Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

Hazard via dermal route: local effects following acute exposure

Justification and comments

In a guideline (OECD TG 404) skin irritation study in rabbits, dipotassium hexachloropalladate produced "slight to moderate" skin irritation (Zechel, 1989a). The compound is classified for skin irritation as Category 2 under CLP. Further, no dose-response data was available from which to derive a DNEL, therefore a qualitative assessment was considered appropriate. At worst this would be considered in the low hazard band according to ECHA (2012b) guidance.

In another guideline (OECD TG 429) study, the structurally-related compound diammonium

hexachloropalladate induced sensitisation in the mouse LLNA. The calculated EC3 value was 11.9% (Valiczko, 2013). This compound is classified for skin sensitisation as Category 1B, under CLP. Accordingly, an identical classification was adopted for dipotassium hexachloropalladate.

According to ECHA (2012b) guidance “moderate skin sensitisers (classified in Sub-category 1B in CLP) are allocated to the moderate hazard category band on the basis that exposure to these moderate skin sensitising substances should be well-controlled”.

Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

Hazard for the eyes

Justification and comments

In a guideline (OECD TG 405) eye irritation study, dipotassium hexachloropalladate produced severe eye irritation and corrosion in a single male rabbit (only one animal was tested) (Zechel, 1989b). The compound is classified 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 (2012b).

Table 5.11. Hazard conclusions for the general population

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

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

Inhalation Systemic effects - Long-term

Further explanation on hazard conclusions:

See discussion section

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

See discussion section

Inhalation Local effects - Long-term

Further explanation on hazard conclusions:

See discussion section

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

See discussion section

Dermal Systemic effects - Long-term

Further explanation on hazard conclusions:

See discussion section

Dermal Systemic effects - Acute

Further explanation on hazard conclusions:

See discussion section

Dermal Local effects - Long-term

Further explanation on hazard conclusions:

See discussion section

Dermal Local effects - Acute

Further explanation on hazard conclusions:

See discussion section

Oral Systemic effects - Long-term

Further explanation on hazard conclusions:

See discussion section

Oral Systemic effects - Acute

Further explanation on hazard conclusions:

See discussion section

Discussion:

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

Related composition: Dipotassium hexachloropalladate (solid and crystalline)

Classification: data conclusive but not sufficient for classification

6.2. Flammability

Flammability

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

Table 6.1. Information on flammability

Method	Results	Remarks
flammability [deactivated phrase] according to UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fifth Edition ; according to Regulation (EC) No 1272/2008 (CLP-/GHS-Regulation)	Study results: Flammable gasses (lower and upper explosion limits): Aerosols: Flammable solids: burning rate test: preliminary screening test (The sample could not be ignited with the gas burner (burning time 2 min) at the preliminary test.) Pyrophoric solids: Pyrophoric liquid: Self-heating substances/mixtures: Substances/ mixture which in contact with water emit flammable gases:	1 (reliable without restriction) key study experimental study **Test material** dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Michael-Schulz 2015**

Discussion

The following information is taken into account for any hazard / risk assessment:
Flammability
Key value for chemical safety assessment: Flammability: non flammable

Dipotassium hexachloropalladate is not classified as a flammable solid as it could not be ignited in the preliminary screening test.

Additional information:

Michael-Schulz (2015) is a non-GLP, guideline study and is considered reliable and suitable for use as the key

study for this endpoint.

Dipotassium hexachloropalladate does not fulfil the criteria of Class 4.1 “Flammable solids” of the UN-TDG and the Hazard Class “Flammable solids” of the Regulation (EC) No 1272/2008 (GHS/CLP) because it could not be ignited in the preliminary screening test.

Flash Point

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

Classification according to GHS

Name: Dipotassium hexachloropalladate

Related composition: Dipotassium hexachloropalladate (solid and crystalline)

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

Justification for classification or non-classification:

Based on a guideline study, dipotassium hexachloropalladate is not classified as a flammable solid.

6.3. Oxidising potential

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

Table 6.2. Information on oxidising potential

Method	Results	Remarks
oxidising properties [deactivated phrase] Contact with: cellulose (3 min) equivalent or similar to Regulation (EC) No 1272/2008 Classification, Labelling and Packaging of Substances and Mixtures, using a procedure designed to be compatible with Test O.1 of United National Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria	Evaluation of results: no oxidising properties - Migrated information Test item has been determined not be a Division 5.1 substance for oxidising properties, as both the 4:1 and 1:1 test item to cellulose test mixtures failed to ignite Test results: Oxidising solids: 1:1 sample-to-cellulose ratio: mean burning time: (mixture does not ignite and burn) 4:1 sample-to-cellulose ratio: mean burning time: (mixture does not ignite and burn) Remarks: Results: 3:7 (by mass) cellulose and potassium bromate reference mixture	1 (reliable without restriction) key study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** hexachloroplatinic acid / 16941-12-1 / 241-010-7, (full information in **Annex II**). **Reference** **Walker JA, White DF 2011**

Test Number	Burning Time (seconds)	Observations
1	91	Mixture burned with an orange and greenish blue flame with some splutterin g
2	138	Mixture burned with an orange and blue flame with splutterin g
3	123	Mixture burned with an orange and blue flame with splutterin g
4	112	Mixture burned with an orange and blue flame with splutterin g
5	114	Mixture burned with an orange and blue flame with splutterin g
1:1 (by mass) test item and cellulose mixture		

1	-	Grey fumes emitted: no ignition. Some charring of the mixture	
2	-	Grey fumes emitted: no ignition. Some charring of the mixture	
3	-	Grey fumes emitted: no ignition. Some charring of the mixture	
4	-	Grey fumes emitted: no ignition. Some charring of the mixture	
5	-	Grey fumes emitted: no ignition. Some charring of the mixture	
4:1 (by mass) test item and cellulose mixture			
1	-	Mixture appears to be boiling and blackenin	

		g. Liquefying observed. No ignition	
	2	-	Mixture appears to be boiling, black liquid. Grey fumes. No ignition
	3	-	Mixture appears to be boiling, black liquid. Grey fumes. No ignition
	4	-	Mixture appears to be charred and melted. Grey fumes. No ignition
	5	-	Mixture appears to be boiling, black liquid. Grey fumes. No ignition
	Test item was fine powder but did contain some larger granules. Whole of test item was ground to a fine powder		
oxidising properties [deactivated phrase] Contact with: powdered cellulose (3 min) equivalent or similar to Test O.1 specified in the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fifth revised edition, 2009	Evaluation of results: no oxidising properties - Migrated information Test results: Oxidising solids: 1:1 sample-to-cellulose ratio: mean burning time: (mixture does not ignite and burn) 4:1 sample-to-cellulose ratio: mean burning time: (mixture does not ignite and burn)		1 (reliable without restriction) key study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase]

Remarks:

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

Test Number	Burning Time (s)	Observations			
1	147	An orange/blue spluttering flame which left dark			

Test material
Tetraammonium decachloro-mu-oxodiruthenate (4-), (full information in **Annex II**).

Reference
Tremain SP, Atwal SS 2011

			grey ash				
	2	139	An orange/blue spluttering flame which left dark grey ash				
	3	116	An orange/blue spluttering flame which left dark grey ash				
	4	133	An orange/blue spluttering				

			flame which left dark grey ash			
5	145	An orange/blue spluttering flame which left dark grey ash				
Results of 4:1 (by mass) test item and cellulose mixtur						

e

Test Number	Burning Time (s)	Observations
1	-	Pale grey smoke, no sign of ignition during the 3 minutes the power was applied
2	-	Dark grey smoke, no sign of ignition during the

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

			n during the 3 minutes the power was applied				
	5	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied				
	Results of 1: 1 (b						

	y mass) test item and cellulose mixture						
	1	-	Pale grey smoke, the pile was slightly charred				
	2	-	Pale grey smoke, the pile was slightly charred				
	3	-	Pale grey sm				

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

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

Authors state that the material, length and diameter of wire met method specifications

	and the appropriate combination of current and voltage was used. therefore as the physical parameters of the wire and the powered dissipation met the method specifications, the deviation from the electrical resistance of the wire had no effect on the test.	

Discussion

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

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

Value used for CSA:
Oxidising properties: no

Additional information:

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

On the basis of read-across dipotassium hexachloropalladate is not classified as an oxidising solid.

Classification according to GHS

Name: Dipotassium hexachloropalladate

Related composition: Dipotassium hexachloropalladate (solid and crystalline)

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

Justification for classification or non-classification:

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

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)	LC50 (96h): 154 µg/L element - palladium (meas. (geom. mean)) based on: mortality (95% CL 102 - 223) LC50 (96h): 306 µg/L test mat. - diamminedichloropalladium (meas. (geom. mean)) based on: mortality (95% CL 203 - 443) LC10 (96h): 180 µg/L test mat. - diamminedichloropalladium (meas. (geom. mean)) based on: mortality LC10 (96h): 90.4 µg/L element - palladium (meas. (geom. mean)) based on: mortality	1 (reliable without restriction) key study experimental study **Test material** 14323-43-4 / 238-269-3, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Teigeler 2012**
Oncorhynchus mykiss (previous name: Salmo gairdneri) freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test)	LC50 (96h): 0.191 mg/L element - palladium (nominal) based on: mortality (Concentration expressed as palladium, determined based on molecular weight coversion) LC50 (96h): 0.53 mg/L test mat. (nominal) based on: mortality (95% Confidence Limits of 0.44-0.64 mg/l) NOEC (96h): >=0.32 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) key study experimental study **Test material** 134620-00-1 / 134620-00-1; Tetrammine Palladium Hydrogen Carbonate, (full information in **Annex II**). **Reference** **Wetton PM 1997**
short-term toxicity to fish		3 (not reliable) disregarded due to major methodological deficiencies experimental study **Test material** Dihydrogen

		tetrachloropalladate, (full information in **Annex II**). **Reference** **Pawlowski, S and Wydra, V 2005**

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)	EC50 (48h): 35.19 µg/L element - palladium (meas. (arithm. mean)) based on: mobility EC50 (48h): 69.91 µg/L test mat. - Diamminedichloropalladium (meas. (arithm. mean)) based on: mobility NOEC (48h): 20.52 µg/L element - palladium (meas. (arithm. mean)) based on: mobility NOEC (48h): 40.77 µg/L test mat. - Diamminedichloropalladium (meas. (arithm. mean)) based on: mobility LOEC (48h): 40.1 µg/L element - palladium (meas. (arithm. mean)) based on: mobility LOEC (48h): 79.67 µg/L test mat. - Diamminedichloropalladium (meas. (arithm. mean)) based on: mobility	1 (reliable without restriction) key study experimental study **Test material** Diamminedichloropalladium (II), Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Schlechtriem 2012**
Daphnia magna freshwater static according to Commission Directive 92/69/EEC Annex Part C, C.2; OECD Guideline 202; OECD Guidance Document for Testing and Assessment, No.23 (Aquatic Toxicity Testing of Difficult Substances and Mixtures).	EC50 (48h): 0.021 mg/L element (nominal) based on: swimming or mortality EC50 (48h): 0.107 mg test item / L test mat. (nominal) based on: swimming or mortality (95% confidence values 0.092-0.125 mg test item/L) EC0 (48h): 0.03 mg test item / L; test mat. (nominal) based on: swimming or mortality EC100 (48h): 0.263 mg test item / L; test mat. (nominal) based on: swimming or mortality NOEC (48h): 0.045 mg test item / L; test mat. (nominal) based on: swimming or mortality LOEC (48h): 0.097 mg test item / L; test mat. (nominal) based on: swimming or mortality	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen tetrachloropalladate (II); palladium(4+) tetrachloride / 16970-55-1 / 241-047-9, Form: liquid (full information in **Annex II**). **Reference** **Moll and Wydra**

		2005
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48h): 46.5 µg/L element (meas. (TWA)) based on: immobility EC50 (24h): 0.29 mg/L test mat. (nominal) based on: Immobility (95% Confidence Limits: 0.26 - 0.33 mg/l) EC50 (48h): 0.22 mg/L test mat. (nominal) based on: Immobility (95% Confidence Limits: 0.20 - 0.25 mg/l) EC50 (24h): 0.18 mg/L test mat. (meas. (TWA)) based on: Immobility (95% Confidence Limits: 0.16 - 0.20) EC50 (48h): 0.13 mg/L test mat. (meas. (TWA)) based on: Immobility (95% Confidence Limits: 0.11 - 0.14) NOEC (24h): 0.18 mg/L test mat. (nominal) based on: Immobility NOEC (48h): 0.1 mg/L test mat. (nominal) based on: Immobility NOEC (24h): 0.12 mg/L test mat. (meas. (TWA)) based on: Immobility NOEC (48h): 0.06 mg/L test mat. (meas. (TWA)) based on: Immobility	2 (reliable with restrictions) key study experimental study **Test material** 134620-00-1 / 134620-00-1; Tetrammine Palladium Hydrogen Carbonate, (full information in **Annex II**). **Reference** **Wetton PM 1997**

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 according to OECD Guideline 211 (Daphnia magna Reproduction Test)	NOEC (21d): >=14.3 µg/L element - Palladium (meas. (TWA)) based on: mortality - growth, reproduction and time to first brood NOEC (21d): >=28.4 µg/L test mat. - DDP (meas. (TWA)) based on: mortality - growth, reproduction and time to first brood	1 (reliable without restriction) key study experimental study **Test material** 14323-43-4 / 238-269-3; Diamminedichloropalladium (II), Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Simon 2014**
Daphnia magna freshwater long-term toxicity to aquatic invertebrates according to OECD Guideline 211 (Daphnia magna Reproduction Test)	EC10 (21d): 35.7 µg/L element (dissolved fraction) - Pd (meas. (TWA)) based on: reproduction - reproduction determined as offspring per survived parent (- 95%CI: 22.3-45.0 µg Pd/L)	1 (reliable without restriction) key study experimental study

	NOEC (21d): 42.7 µg/L element (dissolved fraction) - Pd (meas. (TWA)) based on: reproduction - offspring per survived parent (’reproduction), immobility, length, age of first reproduction and intrinsic rate NOEC (21d): 102 µg/L test mat. (dissolved fraction) - Tetraamminepalladium dichloride (meas. (TWA)) based on: reproduction - offspring per survived parents (’reproduction’), immobility, length, age of first reproduction and intrinsic rate EC10 (21d): 84.9 µg/L test mat. (dissolved fraction) (meas. (TWA)) based on: reproduction - reproduction determined as offspring per survived parent (- 95% CI: 53-107 µg TI/L)	**Test material** Tetraamminepalladium (II) chloride, Form: not specified (full information in **Annex II**). **Reference** **Brüggemann M 2019**

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]	EC10 (72h): 1.88 µg/L element - Palladium (meas. (geom. mean)) based on: growth rate (95% CL 1.29 - 2.24) EC50 (72h): 4.03 µg/L test mat. - Diamminedichloropalladium (meas. (geom. mean)) based on: yield (95% CL 3.58 - 4.85) EC50 (72h): 5.88 µg/L test mat. - Diamminedichloropalladium (meas. (geom. mean)) based on: growth rate (95% CL 5.27 - 6.22) EC50 (72h): 2.03 µg/L element - Palladium (meas. (geom. mean)) based on: yield (95% CL 1.80 - 2.44) EC50 (72h): 2.96 µg/L element - Palladium (meas. (geom. mean)) based on: growth rate (95% CL 2.65 - 3.13) NOEC (72h): 2.64 µg/L test mat. - Diamminedichloropalladium (meas. (geom. mean)) based on: yield NOEC (72h): 2.64 µg/L test mat. - Diamminedichloropalladium (meas. (geom. mean)) based on: growth rate NOEC (72h): 1.33 µg/L element - Palladium (meas. (geom. mean)) based on: yield NOEC (72h): 1.33 µg/L element - Palladium (meas. (geom. mean)) based on: growth rate EC10 (72h): 2.84 µg/L test mat. - Diamminedichloropalladium (meas. (geom. mean)) based on: yield (95% CL 2.50 - 3.16) EC10 (72h): 3.74 µg/L test mat. - Diamminedichloropalladium (meas. (geom. mean)) based on: growth rate (95% CL 2.56	1 (reliable without restriction) key study experimental study **Test material** 14323-43-4 / 238-269-3, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Wenzel 2012**

	- 4.45) EC10 (72h): 1.43 µg/L element - Palladium (meas. (geom. mean)) based on: yield (95% CL 1.26 - 1.59)	
Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to EU Method C.3 (Algal Inhibition test) ; according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]	EC50 (72h): <8.5 µg/L element (estimated) based on: biomass and yield (EC values recalculated based on reported data) NOEC (72h): <5 µg/L element (estimated) based on: biomass and yield (EC values recalculated based on reported data)	2 (reliable with restrictions) key study experimental study **Test material** Dihydrogen tetrachloropalladate (II); palladium(4+) tetrachloride / 16970-55-1 / 241-047-9, Form: liquid (full information in **Annex II**). **Reference** **Pawlowski and Wydra 2005**
Chlamydomonas reinhardtii (algae) freshwater toxicity to aquatic algae and cyanobacteria equivalent or similar to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]	EC50 (96h): 5.7 µg/L element (meas. (geom. mean)) based on: cell number EC10 (96h): 4.48 µg/L element (meas. (geom. mean)) based on: cell number (EC10 re-calculated using Graph & TRAP software; 95% CI: 4.1-4.9) EC50 (24h): 10.1 µg/L element (meas. (geom. mean)) based on: cell number (value as reported in publication) EC50 (48h): 8.7 µg/L element (meas. (geom. mean)) based on: cell number (value as reported in publication) EC50 (72h): 6.5 µg/L element (meas. (geom. mean)) based on: cell number EC10 (72h): 5.06 µg/L element (meas. (geom. mean)) based on: cell number (EC10 re-calculated using Graph & TRAP software; 95% CI: 4.5-5.8)	2 (reliable with restrictions) key study experimental study **Test material** Palladium dichloride dihydrate; palladium(2+) dichloride / 7647-10-1 / 231-596-2, Form: not specified (full information in **Annex II**). **Reference** **Roy G 2009**
Chlamydomonas reinhardtii (algae) freshwater toxicity to aquatic algae and cyanobacteria equivalent or similar to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]	EC50 (24h): 7 µg/L element (meas. (geom. mean)) based on: cell number (pH7.0) EC10 (24h): 3.05 µg/L element (meas. (geom. mean)) based on: cell number (EC10 re-calculated using Graph & TRAP software; 95%CI: 1.6-5.9; pH7) EC50 (24h): 10 µg/L element (meas. (geom. mean)) based on: cell number (pH6.0) EC50 (96h): >=30 µg/L element (nominal) based on: cell number (pH8 - no effect observed at 24, 48, 72 and 96h) EC10 (24h): 5.2 µg/L element (meas. (geom. mean)) based on: cell number (EC10 re-calculated using Graph & TRAP software; 95%CI: 4.8-5.6; pH6)	2 (reliable with restrictions) key study experimental study **Test material** Palladium dichloride dihydrate; palladium(2+) dichloride / 7647-10-1 / 231-596-2, Form: not specified (full information in **Annex II**).

		Reference **Tetrault G 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]	EC50 (72h): 8 µg/L element (meas. (not specified)) based on: biomass (EC50 value recalculated using TRAP based on reported data - 95% CI 7-9) EC10 (72h): 5.3 µg/L element (meas. (not specified)) based on: biomass (EC10 value recalculated using TRAP based on reported data - 95%CI 4-7 µg Pd/L) EC50 (72h): 0.066 mg/L test mat. (nominal) based on: biomass EC50 (24h): 0.078 mg/L test mat. (nominal) based on: growth rate (Extrapolated value) NOEC (72h): 0.04 mg/L test mat. (nominal) based on: growth rate	2 (reliable with restrictions) key study experimental study **Test material** 134620-00-1 / 134620-00-1; Tetrammine Palladium Hydrogen Carbonate, (full information in **Annex II**). **Reference** **Mead C 1997**
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): 4.3 µg/L element (meas. (geom. mean)) based on: growth rate EC10 (72h): 2.7 µg/L element (meas. (geom. mean)) based on: growth rate EC50 (72h): 9.94 µg/L test mat. (meas. (geom. mean)) based on: growth rate (95% CL: 9.02-10.7 µg/L) EC50 (72h): 7.2 µg/L test mat. (meas. (geom. mean)) based on: yield (95% CL 6.46-11.7 µg/L) NOEC (72h): 5.67 µg/L test mat. (meas. (geom. mean)) based on: growth rate and yield EC10 (72h): 6.25 µg/L test mat. (meas. (geom. mean)) based on: growth rate (95% CL: 5.14-7.15 µg/L) EC10 (72h): 4.87 µg/L test mat. (meas. (geom. mean)) based on: yield (95%CL 3.37-5.35 µg/L)	1 (reliable without restriction) key study experimental study **Test material** Tetraamminepalladium (II) chloride, Form: not specified (full information in **Annex II**). **Reference** **Wenzel A 2018**

7.1.4. Sediment organisms

The results are summarised in the following table:

Table 7.5. Effects on sediment organisms

Method	Results	Remarks
Chironomus riparius freshwater sediment toxicity: long-term (laboratory study) static Sediment: artificial sediment according to OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment)	NOEC (28d): >=27.4 mg/kg sediment dw element - Palladium (meas. (arithm. mean)) based on: emergence rate - development rate and development time NOEC (28d): >=54.3 mg/kg sediment dw test mat. - DDP (meas. (arithm. mean)) based on: emergence rate - development rate and development time EC10 (28d): >54.3 mg/kg sediment dw test mat. - DDP (meas. (arithm. mean)) based	1 (reliable without restriction) key study experimental study **Test material** 14323-43-4 / 238-269-3; Diamminedichloropalladium (II),

	on: emergence rate - development rate and development time (95% CL: not determined) EC10 (28d): >27.4 mg/kg sediment dw element - Palladium (meas. (arithm. mean)) based on: emergence rate - development rate and development time (95% CL: not determined) EC50 (28d): >54.3 mg/kg sediment dw test mat. - DDP (meas. (arithm. mean)) based on: emergence rate - development rate and development time (95% CL: not determined) EC50 (28d): >27.4 mg/kg sediment dw element - Palladium (meas. (arithm. mean)) based on: emergence rate - development rate and development time (95% CL: not determined)	Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Simon 2013**

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 7.6. Effects on soil macro-organisms

Method	Results	Remarks
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 - determined as LOEC/2 (effect at first dose is 19%) (28d): 2.5 µmol/L test mat. (nominal) based on: reproduction (- corresponds to 0.05 mg Pd/kg (dry soil)) EC10 - self-calculated from data (28d): 71.3 mg/kg soil dw element (nominal) based on: reproduction EC50 (28d): 21 µmol/L test mat. (nominal) based on: reproduction (corresponding to 0.43 mg Pd/kg(dw)) EC50 - self calculated from data (28d): 584 mg/kg soil dw element (nominal) based on: reproduction	3 (not reliable) supporting study experimental study **Test material** palladium(2+) dichloride / 7647-10-1 / 231-596-2, Form: solid (full information in **Annex II**). **Reference** **Nemcova B. et al. 2013**
Enchytraeus crypticus (Soil dwelling worm) Application method: soil toxicity to terrestrial arthropods: long-term (laboratory study) according to ISO 16387, OECD 220	NOEC - determined as LOEC/2 (effect at first dose 12%) (28d): 2.5 µmol/l test mat. (nominal) based on: mortality (corresponds to 0.05 mg Pd/kg(dwt)) EC10 - self-calculated from data (28d): 102 mg/kg soil dw element (nominal) based on: reproduction	3 (not reliable) supporting study experimental study **Test material** palladium(2+) dichloride / 7647-10-

	EC50 (28d): 70 µmol/L test mat. (nominal) based on: reproduction (corresponds to 1.42 mg Pd/kg(dry soil)) EC50 - self calculated from data (28d): 1947 mg/kg soil dw element (nominal) based on: reproduction	1 / 231-596-2, Form: solution (full information in **Annex II**). **Reference** **Havelkova. B et al. 2014**

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 7.7. 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 7.8. 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): 14590 µg/L element (nominal) based on: inhibition of total respiration - respiration rate NOEC (3h): 18 mg/L test mat. - Diamminedichloropalladium (nominal) based on: inhibition of total respiration - respiration rate EC10 (3h): 29 mg/L test mat. - Diamminedichloropalladium (nominal) based on: inhibition of total respiration - respiration rate (95% CL 28 - 30 mg/L) EC50 (3h): 61 mg/L test mat. - Diamminedichloropalladium (nominal) based on: inhibition of total respiration - respiration rate (95% CL 59 - 63 mg/L)	1 (reliable without restriction) key study experimental study **Test material** 14323-43-4 / 238-269-3, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Muckle 2012**
activated sludge of a predominantly	EC10 (3h): 5260 µg/L element (nominal)	2 (reliable with

domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010]	based on: inhibition of total respiration - respiration rate EC50 (30min): >100 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate EC50 (3h): 35 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate	restrictions) key study experimental study **Test material** 134620-00-1 / 134620-00-1; Tetrammine Palladium Hydrogen Carbonate, (full information in **Annex II**). **Reference** **Mead C, Worth M 1995**
activated sludge of a predominantly domestic sewage freshwater - deionized water, free from inhibitory concentrations of toxic substances (e.g. Cu2+ ions) + synthetic sewage was used. 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): 6900 µg/L element (nominal) based on: inhibition of total respiration - Inhibition based on total microbial respiration rate of the activated sludge NOEC (3h): 15.87 mg/L test mat. (nominal) based on: inhibition of total respiration - Inhibition based on total microbial respiration rate of the activated sludge EC10 (3h): 16.42 mg/L test mat. (nominal) based on: inhibition of total respiration - Inhibition based on total microbial respiration rate of the activated sludge (95% Confidence Interval 11.18-20.73 mg/L) EC50 (3h): 44.64 mg/L test mat. (nominal) based on: inhibition of total respiration - Inhibition based on total microbial respiration rate of the activated sludge (95% Confidence Interval 39.04-51.60 mg/L) EC20 (3h): 23.14 mg/L test mat. (nominal) based on: inhibition of total respiration - Inhibition based on total microbial respiration rate of the activated sludge (95% Confidence Interval 17.66-27.56 mg/L)	1 (reliable without restriction) key study experimental study **Test material** Tetraamminepalladium (II) chloride, Form: not specified (full information in **Annex II**). **Reference** **Simon M 2019**

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 7.9. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 0.045µg/L Intermittent releases:	Assessment factor: 50 Extrapolation method: assessment factor PNEC aqua (freshwater) cfr. PNEC derivation report (IUCLID Section 13)
Marine water	PNEC aqua (marine water): 0.004µg/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): 0.274mg/kg sediment dw	Assessment factor: 100 Extrapolation method: assessment factor PNEC sediment (freshwater) cfr. PNEC derivation report (IUCLID Section 13)
Sediments (marine water)	PNEC sediment (marine water): 0.027mg/kg sediment dw	Assessment factor: 1000 Extrapolation method: assessment factor PNEC sediment (marine water) cfr. PNEC derivation report (IUCLID Section 13)
Sewage treatment plant	PNEC STP: 526µg/L	Assessment factor: 10 Extrapolation method: assessment factor PNEC STP cfr. PNEC derivation report (IUCLID Section 13)
Soil	PNEC soil: 0.02mg/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 this substance as it does 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".

Conclusion on environmental classification

Environmental classification for the soluble metal substances under consideration is based on the lowest acute and chronic threshold values from the Pd ecotoxicity test data:

-chronic ERV: lowest chronic threshold value is 2.26 µg Pd/L (geometric mean EC10 value (growth rate) with P. subcapitata, based on the experimental results for diamminedichloropalladium (EC10 = 1.88 µg Pd/L; Wenzel 2012) and tetraamminepalladium dichloride (EC10=2.72 µg Pd/L; Wenzel 2018))

-acute ERV: lowest acute threshold value is 3.57 µg Pd/L (geometric mean EC50 value (growth rate) with P. subcapitata, based on the experimental results for diamminedichloropalladium (EC50=2.96 µ Pd/L; Wenzel 2012) and tetraamminepalladium dichloride (EC50 = 4.31 µg Pd/L; Wenzel 2018)).

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.

Substance name	Molecular formula	MWt	Pd Wt%	Acute ERV (µg TI/L)	Chronic ERV (µg TI/L)	Acute aquatic hazard	Acute M-factor	Long-term aquatic hazard	Chronic M-factor
Palladium dichloride	PdCl2	177.3	60.0	5.9	3.8	category Acute 1	M=100	category Chronic 1	M=10
Dihydrogen tetrachloropalladate	Cl4Pd.2H	250.2	42.5	8.4	5.3	category Acute 1	M=100	category Chronic 1	M=10
Palladium sulphate	PdSO4	202.5	52.6	6.8	4.3	category Acute 1	M=100	category Chronic 1	M=10
Disodium tetrachloropalladate	Na2PdCl4	294.2	36.2	9.9	6.2	category Acute 1	M=100	category Chronic 1	M=10
Diamminedichloropalladium	Cl2H6N2Pd	211.4	50.3	7.1	4.5	category Acute 1	M=100	category Chronic 1	M=10
Tetraamminepalladium (II) nitrate	H12N4Pd(NO3)2	298.6	35.6	10.0	6.3	category Acute 1	M=10	category Chronic 1	M=10
Tetraamminepalla	H8Cl2N4Pd	241.4	44.1	8.1	5.1	category Acute 1	M=100	category Chronic 1	M=10

dium(2+) dichloride									
Tetraamminepalladium(2+) dihydroxide	H12N4Pd(OH)2	208.6	51.0	7.0	4.4	category Acute 1	M=100	category Chronic 1	M=10
Tetramminepalladium(2+) diacetate	C4H22N4O6Pd	328.7	32.4	11.0	7.0	category Acute 1	M=10	category Chronic 1	M=10
Dipotassium hexachloropalladate	K2PdCl6	397.3	26.8	13.3	8.4	category Acute 1	M=10	category Chronic 1	M=10
Diammonium hexachloropalladate	(NH4)2PdCl6	355.2	30.0	11.9	7.5	category Acute 1	M=10	category Chronic 1	M=10
Tetraamminepalladium(2+) hydrogen carbonate	C2H14O6.N4Pd	296.6	35.9	9.9	6.3	category Acute 1	M=100	category Chronic 1	M=10
Pd acetate	Pd.(C2H3O2)2	224.5	47	7.5	4.8	category Acute 1	M=100	category Chronic 1	M=10

General discussion

This substance is a member of the category of “Palladium & inorganic Palladium 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

No relevant information available.

8.1.2. Summary and overall conclusions on PBT or vPvB properties

Assessment entity linked:
dipotassium hexachloropalladate. View the assessment entity table in chapter 1.3 **here**;
Pd dissolved. View the assessment entity table in chapter 1.3 **here**

Overall conclusion: PBT assessment does not apply.

Justification:

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

8.2. Emission characterisation

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
dipotassium hexachloropalladate for OCC assessment	• 100% dipotassium hexachloropalladate	**Relevant for the assessment of contributing scenarios for:** - Workers/Consumers **Method for calculating the RCR across the AEs:** Summed RCR
Pd dissolved for ENV assessment	• 100% Pd dissolved	**Relevant for the assessment of contributing scenarios for:** - Environment and Man via environment **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: 26.8 tonnes/year based on:
- 26.8 tonnes/year manufactured

Tonnage supplied per market sector:

Manufacture of other substances: 26.8 tonnes/year
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)	26.8		
	- Manufacture of the substance (as such) ES 1.1 (ERC 1)		0.096	26.8
	- Manufacture of the substance (as such) ES 1.2 (ERC 1)		0.096	26.8
	- Manufacture of the substance (as such) ES 1.3		1.8E-3	0.5

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)
	(ERC 1)			
ES2 (IS)	Use as an intermediate	26.8		
	- Use as an intermediate ES 2.1 (ERC 6a)		0.096	26.8
	- Use as an intermediate ES 2.2 (ERC 6a)		0.096	26.8
	- Use as an intermediate ES 2.3 (ERC 6a)		1.8E-3	0.5
ES3 (IS)	Use as an intermediate in the catalyst industry	6.5		
	- Use as an intermediate in the catalyst industry (ERC 6a)		0.023	6.5

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	Pd dissolved	Quantitative	PNEC aqua (freshwater) = 0.045 µg/L
Sediment (freshwater)	Pd dissolved	Quantitative	PNEC sediment (freshwater) = 0.274 mg/kg sediment dw
Marine water	Pd dissolved	Quantitative	PNEC aqua (marine water) = 4.5E-3 µg/L
Sediment (marine water)	Pd dissolved	Quantitative	PNEC sediment (marine water) = 0.027 mg/kg sediment dw
Sewage Treatment Plant	Pd dissolved	Quantitative	PNEC STP = 526 µg/L
Air	Pd dissolved	Not needed	No hazard identified
Agricultural soil	Pd dissolved	Quantitative	PNEC soil = 0.02 mg/kg soil dw
Predator’s prey (freshwater)	Pd dissolved	Not needed	No potential for bioaccumulation
Predator’s prey (marine water)	Pd dissolved	Not needed	No potential for bioaccumulation
Top predator’s prey (marine water)	Pd dissolved	Not needed	No potential for bioaccumulation
Predator’s prey (terrestrial)	Pd 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	Pd dissolved
Molecular weight	≥ 106.4
Molecular weight	106.4

Substance property	Pd dissolved
used for the assessment	
Melting point at 101 325 Pa	450 °C
Vapour pressure	1E-12 Pa at 20 °C
Water solubility	3.41 g/L at 20 °C
Log Kp (solids-water in soil)	2.64 at 25 °C
Log Kp (solids water in sediment)	3.39 at 23 °C
Log Kp (solids-water in suspended matter)	3.39 at 23 °C

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	Pd dissolved
Release to water	26.6%
Release to air	0%
Release to sludge	73.4%
Release degraded	0%

The fractions reported in the above table have been set by the assessor for some assessment entities.
Explanation for Pd dissolved:
Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment.

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 Pd substances submitted local emission and exposure information for locations in Germany, Switzerland, Norway, Belgium the Netherlands, Italy and UK. These sites produce and process a number of different Pd 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 Pd originating from the production/use of Pd metal as well as multiple Pd compounds. A sector approach rather than a substance approach is therefore taken to environmental exposure assessment for Pd.
Monitoring data from the Pd 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 Pd compounds. The use of site-specific monitoring data and representative emission values resulted in RCR values of <1 for all environmental compartments for the manufacturers who also use Pd 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 Pd 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 Pd it is considered that emissions from the manufacture and use of palladium 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 release factors to water and air for manufacture and intermediate use of palladium compounds based on sector data (56 and 22 g/T, respectively) are 13 to 36 times lower than the relevant SpERC-defined release factors (2,000 and 300 g/T for water and air, respectively). An order of magnitude reduction in release estimate is therefore considered to be a reasonably conservative default 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 Pd industry:

Value	Site Tonnage (tpa Pd, 2012-15)	Emission days per site (d/yr)	
		Water	Air
Median (50P)	9.5	280	330
90th % Percentile (90P)	28.0	365	365
Min	-	50	250
Max	-	365	365
n	14	13	13
Selected for Exposure Scenario	28.0 (90P)	280 (50P)	330(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)	56.2	120	25000	6972480	334	32
90P	424	400	177586.5	16000000	13960	641
10P	1.5	3.6	2995	51083.4	22.7	4.31
Min	0.2	1	2950	2950	15	2
Max	833	2592	1344000	16000000	25000	641
N	12	13	10	8	9	7
Selected for ES 1.1 & 2.1 Freshwater – via STP	56.2 (50P)	120 (50P)	3000 (10P STP flow rate)		25 (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)		
Selected for ES 1.3 & 2.3 Marine		On-site: 120 (50P)				100 (default)

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). (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	dipotassium hexachloropalladate	Quantitative	DNEL (Derived No Effect Level) = 5.27 mg/m³
	Systemic effects - acute	dipotassium hexachloropalladate	Not needed	No hazard identified
	Local effects - long term	dipotassium hexachloropalladate	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	dipotassium hexachloropalladate	Qualitative	Medium hazard (no threshold derived)
Dermal	Systemic effects - long term	dipotassium hexachloropalladate	Quantitative	DNEL (Derived No Effect Level) = 1.49 mg/kg bw/day
	Systemic effects - acute	dipotassium hexachloropalladate	Not needed	No hazard identified
	Local effects - long term	dipotassium hexachloropalladate	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	dipotassium hexachloropalladate	Qualitative	Medium hazard (no threshold derived)
Eye	Local effects	dipotassium hexachloropalladate	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 palladium industry, good occupational hygiene practices are followed to ensure safe handling of palladium 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) are 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). QUALITATIVE RISK CHARACTERISATION FOR LOCAL EFFECTS In addition to the quantitative risk characterisation, demonstrating that prescribed operational conditions and risk management measures effectively control exposure well below the respective DNELs, residual exposure concentrations may theoretically still cause local effects. As a precautionary measure, it is therefore prescribed to use personal protective equipment in situations in which such residual exposure concentrations cannot be excluded. The risk of local effects is therefore adequately controlled. Please refer to the document “Methodology applied in the occupational exposure scenarios for palladium substances” as annexed to the CSR for further information on the applied methodology for the occupational exposure assessment.

General information on risk management related to toxicological hazard:

GENERAL INFORMATION RELATED TO PERSONAL PROTECTIVE EQUIPMENT FOR WORKERS Use of personal protective equipment for each of the exposure routes listed below is required as described here, unless exposure to the substance can be excluded for the respective route(s) of exposure. Such exclusion of exposure may be determined by: (i) the physical appearance of the substance in the specific type of application (e.g. wetting the substance can effectively prevent from the emission of dust), (ii) the emission potential resulting from the nature of the process (e.g. splashes, emission of dust can be excluded in a closed process), (iii) applied exposure prevention measures (segregation of the emission source or separation of the worker from the emission source), and (iv) the amount of the handled/emitted material during use in relation to the room size (i.e. dilution factor) under consideration of the prevailing air exchange rates during use. DERMAL ROUTE (SKIN PROTECTION) When dermal protective equipment is required, specific information is provided in the occupational exposure scenarios below. Further, dermal protective equipment is to be selected in consideration of mechanical, cold or heat stress or any other physico-chemical hazards as relevant for the conducted tasks and working environment in addition to the effectiveness of the equipment to control exposure. Certified safety

clothing including coveralls and safety shoes are generally worn. Protective gloves comply with EN 374 and are changed according to manufacturer's information or when damaged, whatever is the earlier. INHALATION ROUTE (RESPIRATORY PROTECTION) When respiratory protective equipment (RPE) is required, specific information on the required assigned protection factor (APF) is provided in the occupational exposure scenarios below. RPE should be selected based on the given APF according to EN 529 and should comply with national legislation. If RPE has to be worn, an APF of 10 represents the required minimum level of protection. RPE shall only be worn if the following principles are implemented in parallel: The duration of work should take into account the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself and due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore: (i) be healthy (especially in view of medical problems that may affect the use of RPE), and (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The devices recommended in the ES which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and supply of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of workers. EYE/FACE PROTECTION Eye/face protective equipment is to be selected in consideration of mechanical, cold or heat stress or any other physico-chemical hazards as relevant for the conducted tasks and working environment in addition to the effectiveness of the equipment to control exposure.

9.0.5. 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
CS 3	Manufacture of the substance (as such) ES 1.3	ERC 1
Worker contributing scenario(s):		
CS 4	Wet chemistry in open or semi-closed processes	PROC 4
CS 5	Handling of solutions/Wet chemistry in open or semi-closed processes	PROC 4
CS 6	Fully contained processes	PROC 1
CS 7	Manual handling of low dusty materials	PROC 26
CS 8	Manual handling of dusty materials	PROC 26
CS 9	Wet cleaning	PROC 8a
CS 10	Vacuum cleaning	PROC 26

Further description of the use:

Dipotassiumhexachloropalladate is produced as an isolated intermediate in the Refining process of palladium. It is obtained by secondary sources. The starting point is a hydrochloric acidic solution of Tetrachloropalladate, which is saturated with chlorine to oxidize Palladium from +II to +IV. Potassium chloride is added to the solution and Dipotassiumhexachloropalladate precipitates as a red, fine/coarse powder. The Dipotassiumhexachloropalladate is filtrated and will be used afterwards in the refining process of Palladium. The salt is 90-99 % pure. Dipotassiumhexachloropalladate as pure substance is obtained in a two-step reaction by dissolving Pd sponge in hydrochloric acid with Chlorine as oxidizing agent and by addition of Potassium Chloride to the chlorine saturated solution afterwards. The salt precipitates as a fine powder.

Explanation on the approach taken for the ES:

It is noted that this exposure scenario focusses on exposure to the substance to be registered. Please refer to information on safe use for the handling of the individual raw materials for process steps preceding the chemical transformation step.

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: Pd dissolved for ENV assessment

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 26.8 tonnes/year *100 tonnes dipotassium hexachloropalladate (26.8 tonnes Pd metal equivalent); Maximum tonnage allowed in registration band.*
• Daily use amount at site: <= 0.096 tonnes/day *Based on 280 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 73.4%]
• Discharge rate of STP: >= 3E3 m3/day
• Application of the STP sludge on agricultural soil: No *The sludge is incinerated (with ash going to landfill)*
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: Other *Dihydrogen tetrachloropalladate- and other Pd -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.*

The sludge from the on-site treatment plant is processed for metal reclamation (recycling).
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 9.3E4 m3/day *based on 50P dilution factor from sector data*
• 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	**Pd dissolved**
Release to water	26.6%
Release to air	0%
Release to sludge	73.4%
Release degraded	0%

Explanation for Pd dissolved:
Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment.

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	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 5.62E-3% **Release factor after on site RMM:** 5.62E-3% **Local release rate:** 5.38E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99.9 % (sector data) Release factor after on-site treatment: 56.2 g/T (50P from sector data)
Air	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.87E-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	Pd 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	Pd dissolved	**Local PEC:** 1.45E-5 mg/L RCR = 0.323	Final RCR = 0.323
Sediment (freshwater)	Pd dissolved	**Local PEC:** 0.036 mg/kg dw RCR = 0.131	Final RCR = 0.131
Sewage Treatment Plant	Pd dissolved	**Local PEC:** 4.77E-4 mg/L RCR = 9.07E-4	Final RCR < 0.01
Agricultural soil	Pd dissolved	**Local PEC:** 2.12E-3 mg/kg dw RCR = 0.107	Final RCR = 0.107

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: Pd dissolved for ENV assessment

9.1.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 26.8 tonnes/year *100 tonnes dipotassium hexachloropalladate (26.8 tonnes Pd metal equivalent); Maximum tonnage allowed in registration band.*
• Daily use amount at site: <= 0.096 tonnes/day *Based on 280 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: Other *Dihydrogen tetrachloropalladate- and other Pd -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.* *The sludge from the on-site treatment plant is processed for metal reclamation (recycling).*
Other conditions affecting environmental exposure
• Discharge to: Freshwater only
• Discharge rate of effluent: >= 3E3 m3/day
• Receiving surface water flow rate: >= 2.98E6 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	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 5.62E-3% **Release factor after on site RMM:** 5.62E-3% **Local release rate:** 5.38E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99.9 % (sector data) Release factor after on-site treatment: 56.2 g/T (50P from sector data)
Air	Pd 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: 2.87E-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	Pd 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	Pd dissolved	**Local PEC:** 1.92E-6 mg/L RCR = 0.043	Final RCR = 0.043
Sediment (freshwater)	Pd dissolved	**Local PEC:** 4.71E-3 mg/kg dw RCR = 0.017	Final RCR = 0.017
Agricultural soil	Pd dissolved	**Local PEC:** 2.12E-3 mg/kg dw RCR = 0.107	Final RCR = 0.107

9.1.3. Env CS 3: Manufacture of the substance (as such) ES 1.3 (ERC 1)

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

9.1.3.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 0.5 tonnes/year *1.87 tonnes dipotassium hexachloropalladate (0.50 tonnes Pd metal equivalent); calculated Msafe*
• Daily use amount at site: <= 1.8E-3 tonnes/day *Based on 280 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: Other *Dihydrogen tetrachloropalladate- and other Pd -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.* *The sludge from the on-site treatment plant is processed for metal reclamation (recycling).*
Other conditions affecting environmental exposure
• Discharge to: Marine water only
• Dilution factor to marine water: <= 100
• Discharge rate of effluent: >= 120 m3/day

9.1.3.2. 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 9.10. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 1E-3% **Release factor after on site RMM:** 1E-3% **Local release rate:** 1.8E-5 kg/day **Explanation:** Arbitrary
Air	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 5.4E-5 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	Pd dissolved	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** No direct emissions to soil.

9.1.3.3. 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 9.11. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Marine water	Pd dissolved	Clocal: 1.2E-6 mg/L (estimated by Calculation with Kp susp. matter marine (logKp = 4.21)) RCR = 0.27	Final RCR = 0.27
Sediment (marine water)	Pd dissolved	Clocal: 0.02 mg/kg dw (estimated by Calculation with Kp susp. matter marine (logKp = 4.21)) RCR = 0.735	Final RCR = 0.735
Agricultural soil	Pd dissolved	**Local PEC:** 1.85E-3 mg/kg dw RCR = 0.094	Final RCR = 0.094

9.1.4. Worker CS 4: Wet chemistry in open or semi-closed processes (PROC 4)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.1.4.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Low	MEASE 1
• Physical form of substance: Solid	MEASE 1
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%]	MEASE 1

	Method
Technical and organisational conditions and measures	
• Contact level: Incidental	MEASE 1
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.1.4.2. Exposure and risks for workers

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

Table 9.12. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	80 µg/m³ (MEASE 1) RCR = 0.015	Final RCR = 0.015
Dermal, systemic, long term	dipotassium hexachloropalladate	3.43 µg/kg bw/day (MEASE 1) RCR = 2.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.017

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.1.5. Worker CS 5: Handling of solutions/Wet chemistry in open or semi-closed processes (PROC 4)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.1.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution, suspension	MEASE 1

	Method
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Very low	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Incidental	MEASE 1
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.1.5.2. Exposure and risks for workers

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

Table 9.13. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	8 µg/m³ (MEASE 1) RCR = 1.52E-3	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	3.43 µg/kg bw/day (MEASE 1) RCR = 2.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.1.6. Worker CS 6: Fully contained processes (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.1.6.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Low	MEASE 1
• Physical form of substance: Solid *Also covering suspensions.*	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: None	MEASE 1
• Level of containment: Closed process	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Closed system without breaches	MEASE 1
• Maximum process temperature: 90 °C	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.1.6.2. Exposure and risks for workers

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

Table 9.14. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	10 µg/m³ (MEASE 1) RCR = 1.9E-3	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	1.71 µg/kg bw/day (MEASE 1) RCR = 1.15E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.1.7. Worker CS 7: Manual handling of low dusty materials (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.1.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	MEASE 1
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Low	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Intermittent	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.1.7.2. Exposure and risks for workers

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

Table 9.15. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	1.5E3 µg/m³ (MEASE 1) RCR = 0.285	Final RCR = 0.285
Dermal, systemic, long term	dipotassium hexachloropalladate	141.4 µg/kg bw/day (MEASE 1) RCR = 0.095	Final RCR = 0.095
Combined routes, systemic, long-term			Final RCR = 0.38

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.1.8. Worker CS 8: Manual handling of dusty materials (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.1.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	MEASE 1
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: High	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Intermittent	MEASE 1
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.1.8.2. Exposure and risks for workers

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

Table 9.16. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	2.2E3 µg/m³ (MEASE 1) RCR = 0.417	Final RCR = 0.417
Dermal, systemic, long term	dipotassium hexachloropalladate	141.4 µg/kg bw/day (MEASE 1) RCR = 0.095	Final RCR = 0.095
Combined routes, systemic, long-term			Final RCR = 0.512

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.1.9. Worker CS 9: Wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.1.9.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution, suspension	MEASE 1
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Very low	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Extensive	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• 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%]	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.1.9.2. Exposure and risks for workers

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

Table 9.17. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Assessment entity**	**Exposure concentration**	**Risk quantification**
Inhalation, systemic, long term	dipotassium hexachloropalladate	50 µg/m³ (MEASE 1) RCR = 9.49E-3	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	34.29 µg/kg bw/day (MEASE 1) RCR = 0.023	Final RCR = 0.023
Combined routes, systemic, long-term			Final RCR = 0.033

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local

effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.1.10. Worker CS 10: Vacuum cleaning (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.1.10.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	MEASE 1
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: High	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Extensive	MEASE 1
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] *Surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner.* Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
• Additional operational conditions for cleaning: No direct manual removal of dust.	MEASE 1
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%]	MEASE 1
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%]	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.1.10.2. Exposure and risks for workers

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

Table 9.18. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Assessment entity**	**Exposure concentration**	**Risk quantification**
Inhalation, systemic, long term	dipotassium hexachloropalladate	80 µg/m³ (MEASE 1) RCR = 0.015	Final RCR = 0.015
Dermal, systemic, long term	dipotassium hexachloropalladate	1.41 µg/kg bw/day (MEASE 1) RCR = 9.46E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.016

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term

For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

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

Market sector: Manufacture of other substances
Sector of use: SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)

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
CS 3	Use as an intermediate ES 2.3	ERC 6a
Worker contributing scenario(s):		
CS 4	Raw material handling	PROC 26
CS 5	Open or semi-closed wet chemical reaction process	PROC 4
CS 6	Wet cleaning	PROC 8a
CS 7	Vacuum cleaning	PROC 26

Explanation on the approach taken for the ES:

It is noted that this exposure scenario focusses on exposure to the substance to be registered. Please refer to information on safe use for the handling of the individual manufactured substances for process steps commencing the chemical transformation step.

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

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

9.2.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 26.8 tonnes/year *100 tonnes dipotassium hexachloropalladate (26.8 tonnes Pd metal equivalent); Maximum tonnage allowed in registration band.*
• Daily use amount at site: <= 0.096 tonnes/day *Based on 280 days per year (50P from sector data)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 73.4%]
• Discharge rate of STP: >= 3E3 m3/day
• Application of the STP sludge on agricultural soil: No *The sludge is incinerated (with ash going to landfill)*
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: Other *Dihydrogen tetrachloropalladate- and other Pd -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.* *The sludge from the on-site treatment plant is processed for metal reclamation (recycling).*
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	Pd dissolved
Release to water	26.6%
Release to air	0%
Release to sludge	73.4%
Release degraded	0%

Explanation for Pd dissolved:
Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment.

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 9.19. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 5.62E-3% **Release factor after on site RMM:** 5.62E-3% **Local release rate:** 5.38E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99.9 % (sector data) Release factor after on-site treatment: 56.2 g/T (50P from sector data)
Air	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.87E-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	Pd 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 9.20. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pd dissolved	**Local PEC:** 1.45E-5 mg/L RCR = 0.323	Final RCR = 0.323
Sediment (freshwater)	Pd dissolved	**Local PEC:** 0.036 mg/kg dw RCR = 0.131	Final RCR = 0.131
Sewage Treatment Plant	Pd dissolved	**Local PEC:** 4.77E-4 mg/L RCR = 9.07E-4	Final RCR < 0.01
Agricultural soil	Pd dissolved	**Local PEC:** 2.12E-3 mg/kg dw RCR = 0.107	Final RCR = 0.107

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: Pd dissolved for ENV assessment

9.2.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 26.8 tonnes/year *100 tonnes dipotassium hexachloropalladate (26.8 tonnes Pd metal equivalent); Maximum tonnage allowed in registration band.*
• Daily use amount at site: <= 0.096 tonnes/day *Based on 280 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: Other *Dihydrogen tetrachloropalladate- and other Pd -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.* *The sludge from the on-site treatment plant is processed for metal reclamation (recycling).*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 2.98E6 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 9.21. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 5.62E-3% **Release factor after on site RMM:** 5.62E-3% **Local release rate:** 5.38E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99.9 % (sector data) Release factor after on-site treatment: 56.2 g/T (50P from sector data)
Air	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 2.87E-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	Pd 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 9.22. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pd dissolved	**Local PEC:** 1.92E-6 mg/L RCR = 0.043	Final RCR = 0.043
Sediment (freshwater)	Pd dissolved	**Local PEC:** 4.71E-3 mg/kg dw RCR = 0.017	Final RCR = 0.017
Agricultural soil	Pd dissolved	**Local PEC:** 2.12E-3 mg/kg dw RCR = 0.107	Final RCR = 0.107

9.2.3. Env CS 3: Use as an intermediate ES 2.3 (ERC 6a)

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

9.2.3.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 0.5 tonnes/year *1.87 tonnes dipotassium hexachloropalladate (0.50 tonnes Pd metal equivalent); calculated Msafe*
• Daily use amount at site: <= 1.8E-3 tonnes/day *Based on 280 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: Other *Dihydrogen tetrachloropalladate- and other Pd -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.* *The sludge from the on-site treatment plant is processed for metal reclamation (recycling).*
Other conditions affecting environmental exposure
• Discharge to: Marine water only
• Discharge rate of effluent: >= 120 m3/day
• Dilution factor to marine water: <= 100

9.2.3.2. 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 9.23. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 1E-3% **Release factor after on site RMM:** 1E-3% **Local release rate:** 1.8E-5 kg/day **Explanation:** Arbitrary
Air	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 3E-3% **Release factor after on site RMM:** 3E-3% **Local release rate:** 5.4E-5 kg/day **Explanation:** Treatment of air emissions by wet scrubbers and filters (e.g. fabric, bag, HEPA).

Release	Assessment entity	Release estimation method	Explanations
			Release factor after on-site treatment: 30 g/T (10% of SpERC RF for 'Manufacture of metal compounds')
Non agricultural soil	Pd dissolved	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** No direct emissions to soil.

9.2.3.3. 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 9.24. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Marine water	Pd dissolved	Clocal: 1.21E-6 mg/L (estimated by Calculation with Kp susp. matter marine (logKp = 4.21)) RCR = 0.273	Final RCR = 0.273
Sediment (marine water)	Pd dissolved	Clocal: 0.02 mg/kg dw (estimated by Calculation with Kp susp. matter marine (logKp = 4.21)) RCR = 0.735	Final RCR = 0.735
Agricultural soil	Pd dissolved	**Local PEC:** 1.85E-3 mg/kg dw RCR = 0.094	Final RCR = 0.094

9.2.4. Worker CS 4: Raw material handling (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.2.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Medium	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Intermittent	MEASE 1
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin	

	Method
(medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.2.4.2. Exposure and risks for workers

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

Table 9.25. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	880 µg/m³ (MEASE 1) RCR = 0.167	Final RCR = 0.167
Dermal, systemic, long term	dipotassium hexachloropalladate	14.14 µg/kg bw/day (MEASE 1) RCR = 9.49E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.176

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.2.5. Worker CS 5: Open or semi-closed wet chemical reaction process (PROC 4)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.2.5.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Very low	MEASE 1
• Physical form of substance: Solution	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Intermittent	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.2.5.2. Exposure and risks for workers

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

Table 9.26. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	50 µg/m³ (MEASE 1) RCR = 9.49E-3	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	3.43 µg/kg bw/day (MEASE 1) RCR = 2.3E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.012

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.2.6. Worker CS 6: Wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.2.6.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Very low	MEASE 1
• Physical form of substance: Solution	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Extensive	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• 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%]	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.2.6.2. Exposure and risks for workers

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

Table 9.27. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	50 µg/m³ (MEASE 1) RCR = 9.49E-3	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	34.29 µg/kg bw/day (MEASE 1) RCR = 0.023	Final RCR = 0.023
Combined routes, systemic, long-term			Final RCR = 0.033

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.2.7. Worker CS 7: Vacuum cleaning (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.2.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	MEASE 1
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: High	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Extensive	MEASE 1

	Method
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] *Surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner.* Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
• Additional operational conditions for cleaning: No direct manual removal of dust.	MEASE 1
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%]	MEASE 1
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%]	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.2.7.2. 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	dipotassium hexachloropalladate	80 µg/m³ (MEASE 1) RCR = 0.015	Final RCR = 0.015
Dermal, systemic, long term	dipotassium hexachloropalladate	1.41 µg/kg bw/day (MEASE 1) RCR = 9.46E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.016

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.3. Exposure scenario 3: Use at industrial sites - Use as an intermediate in the catalyst industry

Market sector: Manufacture of other substances
Sector of use: SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals

Environment contributing scenario(s):		
CS 1	Use as an intermediate in the catalyst industry	ERC 6a
Worker contributing scenario(s):		
CS 2	Raw material handling	PROC 26
CS 3	Fully contained process	PROC 1
CS 4	Closed batch process	PROC 3
CS 5	Small scale handling/transfer of solutions	PROC 9
CS 6	Laboratory analyses	PROC 15
CS 7	Wet cleaning	PROC 8a
CS 8	Vacuum cleaning	PROC 26

Explanation on the approach taken for the ES:

It is noted that this exposure scenario focusses on exposure to the substance to be registered. Please refer to information on safe use for the handling of the individual manufactured substances for process steps commencing the chemical transformation step.

9.3.1. Env CS 1: Use as an intermediate in the catalyst industry (ERC 6a)

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

9.3.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 6.5 tonnes/year *24.3 tonnes dipotassium hexachloropalladate (6.50 tonnes Pd equivalent)*
• Daily use amount at site: <= 0.023 tonnes/day *Based on 280 days per year per site (SpERC)*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 73.4%]
• Discharge rate of STP: >= 2E3 m3/day
• Application of the STP sludge on agricultural soil: No *The sludge is incinerated (with ash going to landfill)*
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: Other *Dihydrogen tetrachloropalladate- and other Pd -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.* *The sludge from the on-site treatment plant is processed for metal reclamation (recycling).*
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 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	Pd dissolved
Release to water	26.6%
Release to air	0%
Release to sludge	73.4%
Release degraded	0%

Explanation for Pd dissolved:
Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Platinum Group Metals in Industrial Effluent during Sewage Treatment.

9.3.1.2. 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 9.29. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 6.7E-3% **Release factor after on site RMM:** 6.7E-3% **Local release rate:** 1.54E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation, electrolysis, reverse osmosis, ion exchange and/or filtration. Efficiency >99% (typical values reported in SpERC for 'Manufacture of metal-containing catalysts') Release factor after on-site treatment: 67 g/T (10% of SpERC RF for wastewater)
Air	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 2.5E-3% **Release factor after on site RMM:** 2.5E-3% **Local release rate:** 5.75E-4 kg/day **Explanation:** Treatment of air emissions by cyclones, filters (e.g. fabric, bag, HEPA or ceramic), electrostatic precipitators and/or wet scrubbers. Efficiency 95 to >99% (typical values reported in SpERC for 'Manufacture of metal-containing catalysts') Release factor after on-site treatment: 25 g/T (10% of SpERC RF for air)
Non agricultural soil	Pd dissolved	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** No direct emissions to soil.

9.3.1.3. 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 9.30. Exposure concentrations and risks for the environment and man via the environment

Protection target	Assessment entity	Exposure concentration	Risk quantification
Fresh water	Pd dissolved	**Local PEC:** 1.99E-5 mg/L RCR = 0.443	Final RCR = 0.443
Sediment	Pd dissolved	**Local PEC:** 0.049 mg/kg dw	Final RCR = 0.179

Protection target	Assessment entity	Exposure concentration	Risk quantification
(freshwater)		RCR = 0.179	
Sewage Treatment Plant	Pd dissolved	**Local PEC:** 2.05E-4 mg/L RCR = 3.9E-4	Final RCR < 0.01
Agricultural soil	Pd dissolved	**Local PEC:** 1.9E-3 mg/kg dw RCR = 0.097	Final RCR = 0.097

9.3.2. Worker CS 2: Raw material handling (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.3.2.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
• Maximum emission potential of the substance: Medium	
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	
• Contact level: Intermittent	
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] Inhalation explanation: *Efficiency for industrial use*	
• Pattern of exposure control: Non-direct handling	
• Pattern of use: Non-dispersive use	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.3.2.2. Exposure and risks for workers

No exposure datasets are defined for this worker contributing scenario.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.3.3. Worker CS 3: Fully contained process (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.3.3.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Very low	MEASE 1
• Physical form of substance: Solution	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: None	MEASE 1
• Level of containment: Closed process	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Closed system without breaches	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.3.3.2. Exposure and risks for workers

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

Table 9.31. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	1 µg/m³ (MEASE 1) RCR = 1.9E-4	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	1.71 µg/kg bw/day (MEASE 1) RCR = 1.15E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.3.4. Worker CS 4: Closed batch process (PROC 3)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.3.4.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Very low	MEASE 1
• Physical form of substance: Solution	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Intermittent	MEASE 1
• Level of containment: Closed process	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.3.4.2. Exposure and risks for workers

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

Table 9.32. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	10 µg/m³ (MEASE 1) RCR = 1.9E-3	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	1.71 µg/kg bw/day (MEASE 1) RCR = 1.15E-3	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.3.5. Worker CS 5: Small scale handling/transfer of solutions (PROC 9)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate

for OCC assessment

9.3.5.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Very low	MEASE 1
• Physical form of substance: Solution	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Intermittent	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.3.5.2. Exposure and risks for workers

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

Table 9.33. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	10 µg/m³ (MEASE 1) RCR = 1.9E-3	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	34.29 µg/kg bw/day (MEASE 1) RCR = 0.023	Final RCR = 0.023
Combined routes, systemic, long-term			Final RCR = 0.025

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.3.6. Worker CS 6: Laboratory analyses (PROC 15)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate

for OCC assessment

9.3.6.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Very low	MEASE 1
• Physical form of substance: Solution	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Intermittent	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (medium hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.3.6.2. Exposure and risks for workers

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

Table 9.34. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	10 µg/m³ (MEASE 1) RCR = 1.9E-3	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	17.14 µg/kg bw/day (MEASE 1) RCR = 0.012	Final RCR = 0.012
Combined routes, systemic, long-term			Final RCR = 0.013

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.3.7. Worker CS 7: Wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate

for OCC assessment

9.3.7.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: Very low	MEASE 1
• Physical form of substance: Solution	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Extensive	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• 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%]	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.3.7.2. Exposure and risks for workers

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

Table 9.35. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	50 µg/m³ (MEASE 1) RCR = 9.49E-3	Final RCR < 0.01
Dermal, systemic, long term	dipotassium hexachloropalladate	34.29 µg/kg bw/day (MEASE 1) RCR = 0.023	Final RCR = 0.023
Combined routes, systemic, long-term			Final RCR = 0.033

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):
Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

9.3.8. Worker CS 8: Vacuum cleaning (PROC 26)

Assessment entity group used for the assessment of this contributing scenario: dipotassium hexachloropalladate for OCC assessment

9.3.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	MEASE 1
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
• Maximum emission potential of the substance: High	MEASE 1
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%]	MEASE 1
Technical and organisational conditions and measures	
• Contact level: Extensive	MEASE 1
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] *Surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner.* Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
• Additional operational conditions for cleaning: No direct manual removal of dust.	MEASE 1
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%]	MEASE 1
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%]	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	

9.3.8.2. Exposure and risks for workers

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

Table 9.36. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	dipotassium hexachloropalladate	80 µg/m³ (MEASE 1) RCR = 0.015	Final RCR = 0.015
Dermal, systemic, long term	dipotassium hexachloropalladate	1.41 µg/kg bw/day (MEASE 1) RCR = 9.46E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR = 0.016

Remarks on exposure data from external estimation tools:

MEASE 1 for dipotassium hexachloropalladate:
Explanation: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term, Dermal, local, acute, Eye, local):

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.
Additional remarks on risk characterisation: Under the prescribed conditions of use, exposure is well below the DNELs and no local effects are expected. Therefore, risks are adequately controlled.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

This chapter describes why a separate risk characterisation related to combined exposure is not required.
Combined exposure may result from any of the following scenarios:
1.Multiple palladium substances handled in parallel at the same workplace,
2.Inhalation and dermal exposure route contributing to systemic effects at the same time,
3.More than just a single contributing occupational exposure scenario relevant for an individual worker,
4.Workers that are also exposed to palladium substances in their free time
These scenarios are considered below:
1. Multiple palladium substances handled in parallel at the same workplace
Exposure monitoring data were obtained from a number of workplaces where palladium and/or palladium substances are manufactured or used in parallel. Any samples are analysed for their palladium content rather than for the content of the respective palladium substance. Thus, measured palladium levels are intrinsically reflective of any potential parallel exposure to multiple palladium substances and are not only relevant for a single palladium substance. An exposure assessment based on such monitoring data can therefore be considered to include an assessment for any palladium substance handled in parallel. For assessments based on modelling tools, it is noted that the handled amount is not considered as input parameter. For small-scale activities as relevant in the palladium industry, it can be assumed that these are covered for all substances handled in parallel by the exposure estimates, which refer to large scale and highly industrialised workplaces.
2. Inhalation and dermal exposure route contributing to systemic effects at the same time
A combined RCR is always maintained significantly below 1 in each of the ES.
3. 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 allexposure 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 exceed the highest calculated RCRfor any of the individual activities in that shift.
4. Workers that are also exposed to palladium substances in their free time (e.g. as member of the general population or as consumer)
For workers who are members of other populations to be protected in this chemical safety assessment (i.e. general population), a specific combined exposure assessment is not required as workers represent a less vulnerable population in comparison to subpopulations (e.g. children) which may be considered in assessments for the general population. Any RCR from these subpopulations could safely be assumed to be in fact significantly lower if re-calculated for workers. In a combined assessment of exposures one would also avoid adding the worst case RCR for workers with the worst case RCR of another population as this would lead to an unrealistic scenario. Instead typical RCRs would be taken which would in combination lead to a low combined RCR.

10.1.2. Consumer

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	Pd dissolved	3.448 kg/year
Air	Pd dissolved	1.771 kg/year
Soil	Pd 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	Pd dissolved	**Regional PEC:** 1.75E-7 mg/L (estimated by External EUSES calculation 2.1.2) RCR = 3.89E-3	Final RCR < 0.01
Sediment (freshwater)	Pd dissolved	**Regional PEC:** 1.53E-3 mg/kg dw (estimated by External EUSES calculation 2.1.2) RCR = 5.58E-3	Final RCR < 0.01
Marine water	Pd dissolved	**Regional PEC:** 1.7E-8 mg/L (estimated by External EUSES calculation 2.1.2) RCR = 3.78E-3	Final RCR < 0.01
Sediment (marine water)	Pd dissolved	**Regional PEC:** 1.52E-4 mg/kg dw (estimated by External EUSES calculation 2.1.2) RCR = 5.55E-3	Final RCR < 0.01
Agricultural soil	Pd dissolved	**Regional PEC:** 1.85E-3 mg/kg dw (Measured data: GEMAS) RCR = 0.094	Final RCR = 0.094

10.2.3. Local exposure due to all widespread uses

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

Annexes

1. Annex: References

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2. Annex: Information on Test Material

Test material: **Palladium (II)**
Form: **gas under pressure: refrigerated liquefied gas**

Composition type:	**Reference substance:** Palladium (II)	**Concentration range:**
Constituent	EC no.: CAS no: IUPAC name: Palladium (II)	

Details on test material: Plasma emission standard, in 1 M HCl Source: BDH

Test material: **Palladium (II)**
Form: **gas under pressure: refrigerated liquefied gas**

Composition type:	**Reference substance:** Palladium (II)	**Concentration range:**
Constituent	EC no.: CAS no: IUPAC name: Palladium (II)	

Details on test material: Pd(NO3)2 in 2-3 % HNO3, ICP standard 1000 ppm solutions (CertiPur, Merck)

Test material: **Palladium (II)**
Form: **gas under pressure: refrigerated liquefied gas**

Composition type:	**Reference substance:** Palladium (II)	**Concentration range:**
Constituent	EC no.: CAS no: IUPAC name: Palladium (II)	

Details on test material: 10000 ppm Pd(II) plasma emission standard in 1.2 M HCl Source: BDH

Test material: **dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6**
Form: **solid: particulate/powder - migrated information: powder**

Composition type:	**Reference substance:** Dipotassium hexachloropalladate	**Concentration range:**
Constituent	EC no.: CAS no: 16919-73-6 IUPAC name:	

Details on test material: - Name of test material (as cited in study report): Potassium hexachloropalladate (IV) - Substance type: Red powder - Physical state: Solid - Analytical purity: 26.8% Pd - Purity test date: Apparently 07 July 1989 - Lot/batch No.: 041368 - Expiration date of the lot/batch: no data - Stability under test conditions: Stable - Storage condition of test material: Kept desiccated in a closed container in a fridge

Test material: **dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6**
Form: **solid: particulate/powder - migrated information: powder**

Composition type:	**Reference substance:** Dipotassium hexachloropalladate	**Concentration range:**
Constituent	EC no.: CAS no: 16919-73-6 IUPAC name:	

Details on test material: - Name of test material (as cited in study report): potassium hexachloropalladate (IV) - Substance type: red powder - Physical state: solid - Analytical purity: 26.8% Pd - Impurities (identity and concentrations): no data - Purity test date: Apparently 07 July 1989 - Lot/batch No.: 041368 - Expiration date of the lot/batch: no data - Stability under test conditions: Stable - Storage condition of test material: kept desiccated in a closed container in a fridge - Other: “substance archives no.”: 87786

Test material: **dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6**
Form:

Composition type:	**Reference substance:** Dipotassium hexachloropalladate	**Concentration range:**
Constituent	EC no.: CAS no: 16919-73-6	

	IUPAC name:	

Details on test material: - Name of test material (as cited in study report): Potassium chloropalladate - Other: no further details given

Test material: **dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** Dipotassium hexachloropalladate EC no.: CAS no: 16919-73-6 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Potassium hexachloropalladate (IV) - Substance type: Red powder - Physical state: Solid - Analytical purity: 26.8% Pd - Impurities (identity and concentrations): no data - Purity test date: Apparently 07 July 1989 - Lot/batch No.: 041368 - Expiration date of the lot/batch: no data - Stability under test conditions: Stable - Storage condition of test material: Kept desiccated in a fridge - Other: slightly soluble in water.

Test material: **diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9**
Form: **solution**

Composition type: Constituent	**Reference substance:** Dipotassium hexachloropalladate EC no.: CAS no: 16919-73-6 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): diammonium hexachloropalladate - Substance type: no data - Physical state: brown-red powder - Analytical purity: ~100% - Impurities (identity and concentrations) (ppm wirth respect to metal): aluminium (3), gold (3), calcium (7), iron (2), potassium (43), sodium (56), platinum (34), rhodium (2), silicon (53), titanium (4) - Composition of test material, percentage of components: palladium at 29.86% - Isomers composition: no data - Purity test date: 7 September 2004 - Lot/batch No.: DP0367 - Expiration date of the lot/batch: 30 September 2024 - Stability under test conditions: stable in propylene glycol for at least 2 hours - Storage condition of test material: room temperature

Test material: **dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6**
Form: **not specified**

Composition type: Constituent	**Reference substance:** dipotassium hexachloropalladate EC no.: 240-974-6 CAS no: 16919-73-6 IUPAC name: dipotassium hexachloropalladate(2-)	**Concentration range:**

Details on test material: None reported

Test material: **diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** Diammonium hexachloropalladate EC no.: CAS no: 19168-23-1 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Diammonium hexachloropalladate - Substance type: no data - Physical state: red powder - Analytical purity: 30.09% (Pd) - Impurities (identity and concentrations): Au (11 ppm); Ca (4 ppm); Fe (1 ppm); K (45 ppm); Na (40 ppm); Rh (1 ppm). - Composition of test material, percentage of components: - Lot/batch No.: DZ0192 - Expiration date of the lot/batch: 07 July 2018 - Stability under test conditions: 4 hours (room temperature) - Storage condition of test material: Room temperature (15-25 deg C, below 70% relative humidity)

Test material: **Dipotassium hexachloropalladate**
Form:

Composition type: Constituent	**Reference substance:** dipotassium hexachloropalladate EC no.: 240-974-6 CAS no: 16919-73-6 IUPAC name: dipotassium hexachloropalladate(2-)	**Concentration range:**

Details on test material: Dipotassium hexachloropalladate(2-)

Test material: **diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9**
Form: **solid - liquid: suspension**

Composition type: Constituent	**Reference substance:** Diammonium hexachloropalladate EC no.: CAS no: 19168-23-1 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): diammonium hexachloropalladate - Substance type: no data - Physical state: brown-reddish crystalline solid - Analytical purity: ~100% - Impurities (identity and concentrations) (ppm with respect to metal): gold (11), calcium (4), iron (1), potassium (45), sodium (40), rhodium (1) - Composition of test material, percentage of components: 30.09% palladium - Isomers composition: no data - Purity test date: 9 July 2013 - Lot/batch No.: DZ0192 - Expiration date of the lot/batch: 7 July 2018 - Stability under test conditions: no data - Storage condition of test material: tightly sealed container at 15-25°C, protected from light

Test material: **diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9**
Form: **solid: crystalline**

Composition type: Constituent	**Reference substance:** Diammonium hexachloropalladate EC no.: CAS no: 19168-23-1 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Diammonium hexachloropalladate - Molecular weight (if other than submission substance): 355.2 - Substance type: technical product - Physical state: brown-reddish crystalline solid - Analytical purity: 30.09% (w/w) palladium content (assumed 100% pure for testing) - Impurities (identity and concentrations): trace levels of gold, calcium, iron, potassium, sodium and rhodium are reported in the certificate of analysis - Composition of test material, percentage of components: no data - Isomers composition: no data - Purity test date: 09 September 2013 - Lot/batch No.: DZ0192 - Expiration date of the lot/batch: 07 July 2018 - Stability under test conditions: no data - Storage condition of test material: 15-25°C in a tightly sealed container, protected from light

Test material: **diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9; dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6**
Form: **solid - liquid: suspension**

Composition type: Constituent	**Reference substance:** Diammonium hexachloropalladate EC no.: CAS no: 19168-23-1 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): diammonium hexachloropalladate - Substance type: no data - Physical state: brown-reddish crystalline solid - Analytical purity: ~100% - Impurities (identity and concentrations) (ppm with respect to metal): gold (11), calcium (4), iron (1), potassium (45), sodium (40), rhodium (1) - Composition of test material, percentage of components: palladium at 30.09% - Isomers composition: no data - Purity test date: 9 July 2013 - Lot/batch No.: DZ0192 - Expiration date of the lot/batch: 7 July 2018 - Stability under test conditions: no data - Storage condition of test material: 15-25°C in a tightly sealed container, protected from light

Test material: **Dipotassiumhexachloropalladate; dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6**
Form:

Composition type: Constituent	**Reference substance:** Dipotassium hexachloropalladate EC no.: CAS no: 16919-73-6 IUPAC name:	**Concentration range:**

Details on test material: Potassiumhexachloropalladate (IV)

Test material: **dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6**
Form: **not specified**

Composition type: Constituent	**Reference substance:** Dipotassium hexachloropalladate EC no.: CAS no: 16919-73-6 IUPAC name:	**Concentration range:**

Details on test material: Dipotassium hexachloropalladate dissolved in distilled water. Molecular formula: K2PdCl6

Test material: **diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** Diammonium hexachloropalladate EC no.: CAS no: 19168-23-1 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Diammonium hexachloropalladate - Substance type: no data - Physical state: red powder - Analytical purity: 30.09% (Pd) - Impurities (identity and concentrations): Au (11 ppm); Ca (4 ppm); Fe (1 ppm); K (45 ppm); Na (40 ppm); Rh (1 ppm). - Lot/batch No.: DZ0192 - Expiration date of the lot/batch: 07 July 2018 - Stability under test conditions: 4 hours (room temperature) - Storage condition of test material: Room temperature (15-25 deg C, below 70% relative humidity)

Test material: **diammonium hexachloropalladate(2-) / 19168-23-1 / 242-854-9**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** Diammonium hexachloropalladate EC no.: CAS no: 19168-23-1 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Diammonium hexachloropalladate - Substance type: no data - Physical state: red powder - Analytical purity: 30.09% (Pd) - Impurities (identity and concentrations): Au (11 ppm); Ca (4 ppm); Fe (1 ppm); K (45 ppm); Na (40 ppm); Rh (1 ppm). - Lot/batch No.: DZ0192 - Expiration date of the lot/batch: 07 July 2018 - Stability under test conditions: 4 hours (room temperature) - Storage condition of test material: Room temperature (15-25 deg C, below 70% relative humidity)

Test material: **dipotassium hexachloropalladate(2-) / 16919-73-6 / 240-974-6**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** dipotassium hexachloropalladate EC no.: 240-974-6 CAS no: 16919-73-6 IUPAC name: dipotassium hexachloropalladate(2-)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Dipotassium hexachloropalladate - Physical state: Solid powder

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

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: **Tetraammonium decachloro-mu-oxodiruthenate (4-)**
Form:

Composition type:	Reference substance:	Concentration range:
Constituent	Tetraammonium decachloro-mu-oxodiruthenate(4-) EC no.: 286-924-7 CAS no: 85392-65-0 IUPAC name: Tetraammonium decachloro-mu-oxodiruthenate(4-)	

Test material: **14323-43-4 / 238-269-3**
Form: **solid: particulate/powder - migrated information: powder**

Composition type:	Reference substance:	Concentration range:
Constituent	Diamminedichloropalladium EC no.: 238-269-3 CAS no: 14323-43-4 IUPAC name: Diamminedichloropalladium	

Details on test material: - Name of test material (as cited in study report): Diamminedichloropalladium (II) - Molecular formula (if other than submission substance): Cl2H6N2Pd - Molecular weight (if other than submission substance): 211.39 g/mole - Physical state: yellow powder - Analytical purity: >99.5% - Composition of test material, percentage of components: 50.33% Palladium - Lot/batch No.: 11011 - Expiration date of the lot/batch: 31 October 2012 - Storage condition of test material: Room temperature (15 - 30°C)

Test material: **134620-00-1 / 134620-00-1; Tetrammine Palladium Hydrogen Carbonate**
Form:

Composition type:	Reference substance:	Concentration range:
Constituent	**Reference substance:** 134620-00-1 EC no.: CAS no: 134620-00-1 IUPAC name: 134620-00-1	
Composition type: Constituent	**Reference substance:** Tetrammine Palladium Hydrogen Carbonate EC no.: CAS no: IUPAC name: Tetrammine Palladium Hydrogen Carbonate	**Concentration range:**

Details on test material: Pale yellow solid, batch No DF0445 received on 12 August 1996 and stored at room temperature shielded from light (not necessarily in darkness).

Test material: **Dihydrogen tetrachloropalladate**
Form:

Composition type:	Reference substance:	Concentration range:
Constituent	**Reference substance:** Dihydrogen tetrachloropalladate EC no.: 241-047-9 CAS no: 16970-55-1 IUPAC name: Dihydrogen tetrachloropalladate	

Test material: **Diamminedichloropalladium (II)**
Form: **solid: particulate/powder - migrated information: powder**

Composition type:	Reference substance:	Concentration range:
Constituent	Diamminedichloropalladium (II) EC no.: CAS no: IUPAC name: Diamminedichloropalladium (II)	

Details on test material: - Name of test material (as cited in study report): Diamminedichloropalladium (II) - Molecular formula (if other than submission substance): Cl2H6N2Pd - Molecular weight (if other than submission substance): 211.39 g/mole - Physical state: yellow powder - Analytical purity: >99.5% - Composition of test material, percentage of components: 50.33% Palladium - Lot/batch No.: 11011 - Expiration date of the lot/batch: 31 October 2012 - Storage condition of test material: Room temperature (15 - 30°C)

Test material: **Dihydrogen tetrachloropalladate (II); palladium(4+) tetrachloride / 16970-55-1 / 241-047-9**
Form: **liquid**

Composition type:	Reference substance: Dihydrogen tetrachloropalladate	Concentration range:
Constituent	EC no.: 241-047-9 CAS no: 16970-55-1 IUPAC name: Dihydrogen tetrachloropalladate	

Details on test material: - Name of test material (as cited in study report): Dihydrogen tetrachloropalladate (II) (in hydrochloric acid) - Substance type: No data - Physical state: Brown liquid - Analytical purity: No data - Impurities (identity and concentrations): Pt (30 ppm); Rh (14 ppm); Ag (9 ppm); Cu (2 ppm); Fe (2 ppm); Pb (3 ppm); Sb (20 ppm); Ru, Ir, Au, Al, Ca, Co, Cr, Mg, Mn, Ni, Si, Sn and Zn (< detection limit) - Composition of test material, percentage of components: Dihydrogen tetrachloropalladate (II) in hydrochloric acid (52.41% w/v; 22.29% w/w palladium content) - Isomers composition: No data - Purity test date: 24 July 2014 - Lot/batch No.: 12614 - Expiration date of the lot/batch: 15 April 2015 - Storage condition of test material: 15-25 deg C, protected from light

Test material: **14323-43-4 / 238-269-3; Diamminedichloropalladium (II)**
Form: **solid: particulate/powder - migrated information: powder**

Composition type:	Reference substance:	Concentration range:
Constituent	Diamminedichloropalladium (II) EC no.: CAS no: IUPAC name: Diamminedichloropalladium (II)	
Composition type: Constituent	**Reference substance:** Diamminedichloropalladium EC no.: 238-269-3 CAS no: 14323-43-4 IUPAC name: Diamminedichloropalladium	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Diamminedichloropalladium (II) - Molecular formula (if other than submission substance): Cl2H6N2Pd - Molecular weight (if other than submission substance): 211.39 g/mole - Physical state: yellow powder - Analytical purity: >99.5% - Composition of test material, percentage of components: 50.35% Palladium - Lot/batch No.: 10912 - Expiration date of the lot/batch: 28 August 2014 - Storage condition of test material: Room temperature (15 - 30°C)

Test material: **Tetraamminepalladium (II) chloride**
Form: **not specified**

Composition type:	Reference substance:	Concentration range:
Constituent	Tetraamminepalladium (II) chloride EC no.: CAS no: IUPAC name: Tetraamminepalladium (II) chloride	

Test material: **14323-43-4 / 238-269-3**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** Diamminedichloropalladium EC no.: 238-269-3 CAS no: 14323-43-4 IUPAC name: Diamminedichloropalladium	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Diamminedichloropalladium (II) - Molecular formula (if other than submission substance): Cl2H6N2Pd - Molecular weight (if other than submission substance): 211.39 g/mole - Physical state: yellow powder - Analytical purity: >99.5% - Composition of test material, percentage of components: 50.33% Palladium - Lot/batch No.: 11011 - Expiration date of the lot/batch: 31 October 2012 - Storage condition of test material: Room temperature (15 - 30°C)

Test material: **Palladium dichloride dihydrate; palladium(2+) dichloride / 7647-10-1 / 231-596-2**
Form: **not specified**

Composition type: Constituent	**Reference substance:** Palladium dichloride dihydrate EC no.: CAS no: IUPAC name: Palladium dichloride dihydrate	**Concentration range:**
Composition type: Constituent	**Reference substance:** Palladium dichloride EC no.: 231-596-2 CAS no: 7647-10-1 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): PdCl2.2(H2O) - Substance type: No data - Physical state: No data - Analytical purity: No data - Impurities (identity and concentrations): No data - Composition of test material, percentage of components: No data - Isomers composition: No data - Purity test date: No data - Lot/batch No.: No data - Expiration date of the lot/batch: No data - Stability under test conditions: No data - Storage condition of test material: No data

Test material: **134620-00-1 / 134620-00-1; Tetrammine Palladium Hydrogen Carbonate**
Form:

Composition type: Constituent	**Reference substance:** 134620-00-1 EC no.: CAS no: 134620-00-1 IUPAC name: 134620-00-1	**Concentration range:**
Composition type: Constituent	**Reference substance:** Tetrammine Palladium Hydrogen Carbonate EC no.: CAS no: IUPAC name: Tetrammine Palladium Hydrogen Carbonate	**Concentration range:**

Details on test material: Pale yellow solid, batch No DF0445 received on 12 August 1996 and stored at room temperature shielded from light (not necessarily in darkness).

Test material: **palladium(2+) dichloride / 7647-10-1 / 231-596-2**
Form: **solid**

Composition type: Constituent	**Reference substance:** palladium dichloride EC no.: 231-596-2 CAS no: 7647-10-1 IUPAC name: palladium(2+) dichloride	**Concentration range:**

Test material: **palladium(2+) dichloride / 7647-10-1 / 231-596-2**

Form: **solution**

Composition type: Constituent	**Reference substance:** palladium dichloride EC no.: 231-596-2 CAS no: 7647-10-1 IUPAC name: palladium(2+) dichloride	**Concentration range:**

Test material: **14323-43-4 / 238-269-3**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** Diamminedichloropalladium EC no.: 238-269-3 CAS no: 14323-43-4 IUPAC name: Diamminedichloropalladium	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Diamminedichloropalladium - Molecular formula (if other than submission substance): C12H6N2Pd - Molecular weight (if other than submission substance): 211.39 g/mol - Physical state: Yellow powder - Analytical purity: >99.5% - Composition of test material, percentage of components: 50.33% palladium - Lot/batch No.: 11011 - Expiration date of the lot/batch: 31 October 2012 - Storage condition of test material: Closed dry vessel at room temperature

Test material: **134620-00-1 / 134620-00-1; Tetrammine Palladium Hydrogen Carbonate**
Form:

Composition type: Constituent	**Reference substance:** 134620-00-1 EC no.: CAS no: 134620-00-1 IUPAC name: 134620-00-1	**Concentration range:**
Composition type: Constituent	**Reference substance:** Tetrammine Palladium Hydrogen Carbonate EC no.: CAS no: IUPAC name: Tetrammine Palladium Hydrogen Carbonate	**Concentration range:**

Details on test material: Pale yellow solid, batch No DD0247 received on 25 January 1995 and stored at room temperature in a black plastic tube.

3. Annex: Mode of action / Human relevance Framework

Section 5.6.3: Repeated dose toxicity
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:

Section 5.9.3: Toxicity to reproduction
Detailed information on mode of action / Human relevance framework: