CHEMICAL SAFETY REPORT

Substance Name: dihydrogen tetrachloropalladate(2-)
EC Number: 241-047-9
CAS Number: 16970-55-1
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

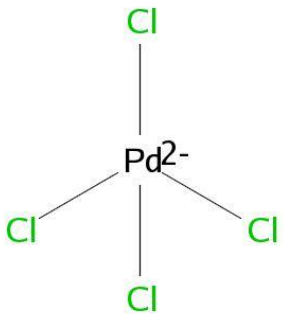
1.1. Name and other identifiers of the substance

The substance dihydrogen tetrachloropalladate(2-) is a mono-constituent substance (inorganic) having the following characteristics and physical-chemical properties (see the IUCLID dataset for further details).

Table 1.1. Substance identity

IUPAC name:	palladium(4+) tetrachloride
Synonyms:	Synonyms Palladate(2-), tetrachloro-, dihydrogen, (SP-4-1)-
EC number:	241-047-9
EC name:	dihydrogen tetrachloropalladate(2-)
CAS number (EC inventory):	16970-55-1
CAS number:	16970-55-1
Molecular formula:	Cl4Pd.2H
Molecular weight:	248.232

Figure 1.1. 16970-55-1-V2.jpeg



1.2. Composition of the substance

Overall information on composition:

Composition	Related composition(s)	Related assessment entity
dihydrogen tetrachloropalladate(2-) (legal entity composition of the substance)		Dihydrogen tetrachloropalladate(2-)
dihydrogen tetrachloropalladate(2-) (boundary composition of the substance)		Dihydrogen tetrachloropalladate(2-) Pd dissolved

Name: dihydrogen tetrachloropalladate(2-)

(legal entity composition of the substance)
State/form: Solution
Degree of purity: % (w/w)
Description: Dihydrogen tetrachloropalladate is produced by dissolving PdCl2 in Hydrochloric acid solution, followed by filtration of insoluble parts. Material is only stable in hydrochloric acid solution.

Table 1.2. Constituents (dihydrogen tetrachloropalladate(2-))

Constituent	Typical concentration	Concentration range	Remarks
dihydrogen tetrachloropalladate(2-) EC no.: 241-047-9	% (w/w)	% (w/w)	The most concentrated existing solution contains 59% H2PdCl4, which means that 41% of solvent is needed to keep the H2PdCl4 stabilized. The solvent in this case is diluted hydrochloric acid (H2O + HCl).

Table 1.3. Impurities (dihydrogen tetrachloropalladate(2-))

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.

Table 1.4. Additives (dihydrogen tetrachloropalladate(2-))

Constituent	Function	Typical concentration	Concentration range	Remarks
water EC no.: 231-791-2	stabiliser: other	% (w/w)	% (w/w)	
hydrogen chloride EC no.: 231-595-7	stabiliser: other	% (w/w)	% (w/w)	

Name: dihydrogen tetrachloropalladate(2-)

(boundary composition of the substance)
State/form: Solution
Degree of purity: >=24 - <=59 % (w/w)
Description: Dihydrogen tetrachloropalladate is produced by dissolving PdCl2 in Hydrochloric acid solution, followed by filtration of insoluble parts. Material is only stable in hydrochloric acid solution.

Table 1.5. Constituents (dihydrogen tetrachloropalladate(2-))

Constituent	Typical concentration	Concentration range	Remarks
dihydrogen tetrachloropalladate(2-) EC no.: 241-047-9	47 % (w/w)	>=24 - <=59 % (w/w)	The most concentrated existing solution contains 59% H2PdCl4, which

			means that 41% of solvent is needed to keep the H2PdCl4 stabilized. The solvent in this case is diluted hydrochloric acid (H2O + HCl).

Table 1.6. Impurities (dihydrogen tetrachloropalladate(2-))

Constituent	Typical concentration	Concentration range	Remarks
Several minor impurities EC no.:	<0.1 % (w/w)	>=0 - <=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.

Table 1.7. Additives (dihydrogen tetrachloropalladate(2-))

Constituent	Function	Typical concentration	Concentration range	Remarks
water EC no.: 231-791-2	stabiliser: other	35 % (w/w)	>=28 - <=51 % (w/w)	
hydrogen chloride EC no.: 231-595-7	stabiliser: other	18 % (w/w)	>=13 - <=25 % (w/w)	

Justification for reporting set of similar nanoforms:

Shape
No information available on Shape from IUCLID

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

Crystallinity
No information available on Crystallinity in IUCLID

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

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

Justification for reporting set of similar nanoforms:

Shape
No information available on Shape from IUCLID

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

Crystallinity
No information available on Crystallinity in IUCLID

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

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

1.3. Assessment entity information

Assessment entity name	Remarks
Dihydrogen tetrachloropalladate(2-)	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. Information on linked categories

1.5. Physicochemical properties

Table 1.8. Physicochemical properties

Property	Value used for CSA / Discussion	Description of key information	Assessment entity linked
Physical state	**liquid at 20°C and 101.3 kPa** Statement on the appearance of the substance has been provided by the Lead Registrant (Fuchs 2021). Dihydrogen tetrachloropalladate(2 -) is only stable in solution. The colour of the solution can range between brown and yellow. The most concentrated solution contains 59% of H2[PdCl4]. When	This substance is only stable in solution.	

	trying to further concentrate the solution, e.g. by evaporation on a water bath, H2O and HCl starts to evolve. In addition, the H2[PdCl4] hydrolyses to palladium chloride hydroxide moieties (e.g. PdCl2.HCl.H2O or H2PdCl3(OH).H2O) and palladium dihydroxide.		
Melting / freezing point	**-70.7°C at 101.3 kPa** Nau (2017) is a GLP-compliant study following OECD guideline 102 and EU method A1. It is considered suitable for use as the key study for this endpoint. Dihydrogen tetrachloropalladate has a mean melting point of -70.7°C.	Dihydrogen tetrachloropalladate has a mean melting point of -70.7°C.	Pd dissolved
Boiling point	**112°C at 101.3 kPa** Nau (2017) is a GLP-compliant study following OECD guideline 103 and EU method A2. It is considered suitable for use as the key study for this endpoint. Dihydrogen tetrachloropalladate has a boiling range of 112 to 116°C. The boiling was incomplete (mass loss: 67 %).	Dihydrogen tetrachloropalladate has a boiling range of 112 to 116°C. The boiling was incomplete (mass loss: 67 %).	
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	**10g/L at 20°C** The water solubility of the test item was determined in a non-GLP, modified guideline water solubility study (Gregory 2014). The study is considered to be suitable for use as the key study for this endpoint. The water solubility of dihydrogen tetrachloropalladate has been determined to be > 10 g/L of solution.	The water solubility of dihydrogen tetrachloropalladate has been determined to be > 10 g/L of solution.	Pd dissolved
Flash point	Nau (2017) is a GLP-compliant study following EU method A9. It is considered suitable for use as the key study for this endpoint. No flashpoint was observed for	No flashpoint was observed for dihydrogen tetrachloropalladate up to 120°C. Afterwards boiling was observed.	

	dihydrogen tetrachloropalladate up to 120°C. Afterwards boiling was observed.		
Autoflammability / self-ignition temperature	Nau (2017) is a GLP-compliant study following EU method A15. It is considered suitable for use as the key study for this endpoint. Dihydrogen tetrachloropalladate showed no ignition up to 653°C. As no ignition was observed in the preliminary test, the main test was not required.	Dihydrogen tetrachloropalladate showed no ignition up to 653°C.	

Data waiving

Information requirement: Relative density

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent [study scientifically not necessary / other information available] - The substance is an aqueous solution of an inorganic salt and the relative density is similar to, but slightly higher than, that of the solvent.

Information requirement: Granulometry

Reason: study scientifically not necessary / other information available

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

Information requirement: Vapour pressure

Reason: study scientifically not necessary / other information available

Justification: The substance is an aqueous solution of an inorganic salt and the vapour pressure is similar to that of the solvent.

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: Flammability

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is a liquid [study technically not feasible] - In accordance with REACH Annex XI, it is not scientifically justifiable to conduct this study as this substance is in an aqueous solution. The flash point indicates that this substance is not classified as a flammable liquid.

Information requirement: Explosive properties

Reason: study scientifically not necessary / other information available

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

Information requirement: Oxidising properties

Reason: study scientifically not necessary / other information available

Justification: See 'Remark' - In accordance with REACH Annex XI, testing is not considered to be scientifically justifiable based on expert opinion and information for other transition metal compounds, which lead to the conclusion that the substance will not be oxidising. To assess the oxidising properties of platinum group metals, categories of substances were identified and this substance was assigned the category 'Halogens with a metal2+ oxidation state'. The category contains substances with chloride ligands some of which also contain organic components with no structural alerts for oxidising properties. Other members of this category have ammine and chloride present in the substance. In the case of Tetraammineplatinum dichloride and Tetraamminepalladium dichloride, the chloride is merely a counter ion and is not even coordinated to the metal. The proximity of ammine and chloride in the same molecule is also irrelevant for this end point. Metal ammine complexes and simple ammonium halides, including ammonium chloride are not classified as oxidants, too. The only time that ammines become an issue is when they are adjacent to genuine strong oxidants, such as nitrate, as evidenced by ammonium nitrate and then only in the presence of an easily oxidisable component such as a carbon source. An alternative example is the case of Tetraammineplatinum dinitrate, which is potentially explosive when dry. These substances are therefore categorised solely according to the chloride ligands which can be of potential concern for this endpoint. One substance from this category, tetraammineplatinum dichloride, has been tested for oxidising properties and was non-oxidising; other members of the category are also considered to be non-oxidising. There is substantial evidence that directly comparable metal chlorides are also non-oxidizing. Other Group VIII transition metals, such as cobalt(II) chloride, iron II), iron(III) and nickel(II) chloride have no classification for oxidizing properties. Copper(I) chloride from the adjacent transition 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. In addition, hexachloroplatinic acid (4+ category) and rhodium triiodide (3+ category), containing precious metals in a higher oxidation state, have been tested for oxidising properties and found to be non-oxidising.

Discussion of physicochemical properties

Additional information:
This substance is only stable in solution, and therefore physico-chemical endpoints have been completed on this basis. Physico-chemical endpoints have been completed using test data and appropriate data waivers.

This substance is classified as Metal corrosivity category 1 (H290) based on expert judgment due to the extreme low pH of the substance.

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: Dihydrogen tetrachloropalladate is produced by dissolving PdCl2 in Hydrochloric acid solution, followed by filtration of insoluble parts. Material is only stable in hydrochloric acid solution. 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 : **- Fully contained processes (PROC 1)** **- Wet chemistry in open or semi-closed processes (PROC 4)** **- Handling/Transfer of solutions (PROC 8b)** **- Small scale handling/transfer of solutions (PROC 9)** **- Wet cleaning (PROC 8a)** use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Related assessment: use assessed in a joint CSR

2.2. Identified uses

Table 2.2. Formulation

	Formulation
F-1	**Formulation** Further description of the use: Contributing activity/technique for the environment : **- Formulation (ERC2)** Contributing activity/technique for the workers : **- Handling/Transfer of solutions (PROC 8b)** **- Small scale handling/transfer of solutions (PROC 9)** **- Formulation step (PROC 4)** **- Wet cleaning (PROC 8a)** **Product Category formulated:** PC 14: Metal surface treatment products **Technical function of the substance:** no technical function 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 Related assessment: use assessed in a joint CSR

Table 2.3. 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 : **- Handling/Transfer of solutions (PROC 8b)** **- Small scale handling/transfer of solutions (PROC 9)** **- Fully contained process (PROC 1)** **- Batch process in closed system (PROC 3)** **- Open or semi-closed wet chemical process (PROC 4)** **- Laboratory analyses (PROC 15)** **- Wet cleaning (PROC 8a)** **Sector of end use:** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) ; SU 9: Manufacture of fine chemicals ; SU 14: Manufacture of basic metals, including alloys **Technical function of the substance:** intermediate (precursor) use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Substance supplied to that use: as such ; in a mixture Subsequent service life relevant for that use: no Related assessment: use assessed in a joint CSR
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 : **- Small scale handling/transfer of solutions (PROC 9)** **- Fully contained process (PROC 1)** **- Closed batch process (PROC 3)** **- Laboratory analyses (PROC 15)** **- Wet cleaning (PROC 8a)** **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
IW-3	**Use in metal surface treatment** Further description of the use: Contributing activity/technique for the environment : **- Use in metal surface treatment (ERC5)** Contributing activity/technique for the workers : **- Handling/Transfer of solutions (PROC 8b)** **- Small scale handling/transfer of solutions (PROC 9)** **- Open or semi-closed wet chemical process (PROC 4)** **- Plating (PROC 13)** **- Wet cleaning (PROC 8a)** **Product Category used:** PC 14: Metal surface treatment products **Sector of end use:** SU 15: Manufacture of fabricated metal products, except machinery and equipment **Technical function of the substance:** plating agents and metal surface treating agents 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: yes Link to the subsequent service life: Service life of treated articles Related assessment: use assessed in a joint CSR

Table 2.4. Article service life

	Article service life
SL-1	**Service life of treated articles** Further description of the use: Treated articles do not contain dihydrogen tetrachloropalladate but palladium in metallic form. Article used by: consumers Substance intended to be released from article: no **Article category related to subsequent service life (AC):** Contributing activity/technique for the environment: **- Service life of treated articles (ERC10a ; ERC11a)** Contributing activity/technique for consumers: **- Service life of treated articles (AC 7)** Contributing activity/technique for the workers: **Technical function of the substance:** Palladium is plated on an article 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

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Substance: Dihydrogen tetrachloropalladate (2-)
Implementation: EU
Related composition: Boundary composition

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

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

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

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

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:	Acute Tox. 4	H302: Harmful if swallowed.	
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:	Skin Corr. 1A	H314: Causes severe skin burns and eye damage.	
Serious damage / eye irritation:	Eye Damage 1	H318: Causes serious eye damage.	
Respiratory sensitisation:			data lacking
Skin sensitisation:	Skin Sens. 1A	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 conclusive but not sufficient for classification
Germ cell mutagenicity:			data conclusive but not sufficient for classification
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:			data conclusive but not sufficient for classification
Specific target organ toxicity – repeated exposure:			data conclusive but not sufficient for classification

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

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):	Aquatic Acute 1	H400: Very toxic to aquatic life.	
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects.	
M-Factor acute: 100			
M-Factor chronic: 10			
Hazardous to the ozone			data conclusive but not

layer:			sufficient for classification

Labelling

Signal word: Danger

Hazard pictogram:

GHS05: corrosion

GHS07: exclamation mark

GHS09: environment

Hazard statements:

H290: May be corrosive to metals.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H317: May cause an allergic skin reaction.

H400: Very toxic to aquatic life.

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

Precautionary statements:

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

P102: Keep out of reach of children.

P103: Read carefully and follow all instructions.

P234: Keep only in original packaging.

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

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

P264: Wash ... thoroughly after handling.

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

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

P273: Avoid release to the environment.

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

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

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

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

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

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

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

P310: Immediately call a POISON CENTER/doctor/…

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

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.

P390: Absorb spillage to prevent material damage.

P391: Collect spillage.

P405: Store locked up.

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

P501: Dispose of contents/container to ...

Additional labelling requirements (CLP supplemental hazard statement):

EUH071: Corrosive to the respiratory tract. [European Union]

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

Key Information:
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.

Standard test methods for hydrolysis are not considered to be appropriate for inorganic substances. However, information taken from the ecotoxicity studies conducted with this substance (Moll and Wydra 2005, Pawlowski 2005) indicates that the test substance hydrolyses quickly (<1 hour).

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

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.

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. However, information taken from the ecotoxicity studies conducted with this substance (Moll and Wydra 2005, Pawlowski 2005) indicates that the test substance hydrolyses quickly (<1 hour).

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available.

4.1.1.2.2. Phototransformation in water

No relevant information available.

4.1.1.2.3. Phototransformation in soil

No relevant information available.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

No relevant information available.

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: study technically not feasible

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

4.1.2.1.2. Simulation tests (water and sediments)

No relevant information available.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

No relevant information available.

4.1.2.2. Biodegradation in soil

No relevant information available.

4.1.3. Summary and discussion of degradation

4.2. Environmental distribution

4.2.1. Adsorption/desorption

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

Table 4.1. Studies on adsorption/desorption

Method	Results	Remarks
adsorption / desorption [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:	2 (reliable with restrictions) supporting study experimental study **Test material** Palladium (II), Form: gas under

	Transformation products:	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:

Key Information:
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.

4.2.4. Summary and discussion of environmental distribution

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

No relevant information available.

4.3.2. Terrestrial bioaccumulation

No relevant information available.

4.3.3. Summary and discussion of bioaccumulation

4.4. Secondary poisoning

Based on the available information, 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:

Key Information:
With its relatively low molecular weight (~250 g/mol) and, more critically, high water solubility (>10,000 mg/L), it is likely that dihydrogen tetrachloropalladate will be absorbed (as the ions) from the gastro intestinal tract. As such, predicted oral absorption of dihydrogen tetrachloropalladate is conservatively set at 100%.

Although not expected to reach the lungs in appreciable quantities (since the substance is marketed as a solution and the concept of vapour pressure is irrelevant for this compound), as a highly water soluble substance with a relatively low molecular weight, any dihydrogen tetrachloropalladate that does reach the lungs is likely to be absorbed through aqueous pores. As such, the predicted inhalation absorption is conservatively set at 100%.

Dihydrogen tetrachloropalladate, with water solubility in excess of 10,000 mg/L, may be unable to cross the lipid-rich environment of the stratum corneum. However, the compound is classified for skin corrosion in sub-category 1A. This corrosive 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 the highly 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 (~250 g/mol) and, more critically, the high estimated water solubility (>10,000 mg/L; Gregory, 2014) are indicative of a high bioavailability of dihydrogen tetrachloropalladate by this route. A

health-precautionary assumption is that the ions will be absorbed from the gastro-intestinal tract. As such, predicted oral absorption of dihydrogen tetrachloropalladate is set at 100%.

In the acute oral toxicity test on dihydrogen tetrachloropalladate, the liver, abdominal cavity and kidney findings at necropsy, as well as a general reduction in body weight and a variety of clinical signs of toxicity (van Huygevoort, 2003a), are indicative of at least partial oral absorption. Effects in a combined repeated dose and reproductive/developmental toxicity dietary study in rats, on the a category ("tetraamminepalladium salts") member disodium tetrachloropalladate, included reductions in body weight, growth, food consumption and relative weights of various organs (Szaloki 2022). These results are indicative of a potential for some oral absorption of the test substances (and thus possibly of dihydrogen tetrachloropalladate).

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 that the substance is an aqueous solution of an inorganic salt and the vapour pressure is similar to that of the solvent. Particle size distribution testing was waived as the substance is marketed in "a non-solid or granular form" (as a solution). Accordingly, inhalation is not considered to be a significant route of exposure. However, as a highly water soluble substance (>10,000 mg/L), any dihydrogen tetrachloropalladate 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 dihydrogen tetrachloropalladate 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 high water solubility of dihydrogen tetrachloropalladate (>10,000 mg/L), it is unlikely to be able to cross the lipid-rich environment of the stratum corneum. In spite of this, 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, dihydrogen tetrachloropalladate is classified as corrosive (to skin) sub-category 1A. This is based on a mean breakthrough time of about 3 minutes in an in vitro membrane barrier test (Lehmeier, 2013). Such corrosive 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 acute dermal toxicity or in vivo skin irritation tests were conducted on dihydrogen tetrachloropalladate due to its classification as corrosive to the skin in an in vitro membrane barrier test (Lehmeier, 2013). The existing in vivo skin sensitisation study (van Huygevoort, 2003b), albeit limited in its assessment of systemic effects, did not lead to overt systemic toxicity. Given the toxicity observed following ingestion, this is a limited indication that the substance will not be well-absorbed dermally.

Distribution/Metabolism
Once absorbed, distribution of hydrogen/hydroxonium ions and tetrachloropalladate ions throughout the body is expected based on a relatively low molecular weight.

In the acute oral toxicity test on dihydrogen tetrachloropalladate, necropsy of deceased animals revealed findings in the liver, abdominal cavity and kidneys (van Huygevoort, 2003a), suggesting possible distribution to these tissues.
In a combined repeated dose and reproductive/developmental toxicity dietary study in rats on disodium tetrachloropalladate, a category member substance, reductions in the relative weight of adrenal glands, thyroid/parathyroid glands, seminal vesicles, ovaries, liver, brain and heart, but these were considered not biologially relevant or due to excessive toxicity (dosing in excess of MTD) and were histologically considered

as non adverse or incidental (Szaloki 2022).
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).
Dihydrogen tetrachloropalladate has characteristics favourable for rapid excretion: low molecular weight (below 300 g/mol) and 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, dihydrogen tetrachloropalladate is considered to have only a low potential for bioaccumulation based on its predicted physico-chemical properties (i.e. water solubility >10,000 mg/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, dihydrogen tetrachloropalladate is likely partially bioavailable by the oral route and rapidly excreted once absorbed. A high dermal bioavailability is anticipated on the basis that its corrosive potential may disrupt skin barrier function, facilitating dermal penetration. Although bioavailability by the inhalation route is anticipated to be low (since the substance is marketed as a solution), inhalation absorption is considered a possibility based on its low molecular weight and high water solubility. Proposed predicted absorption figures for the oral, dermal and inhalation routes are all conservatively set at 100%.

References not included elsewhere:

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

Iavicoli I, Bocca B, Fontana L, Caimi S, Bergamaschi A and Alimonti A (2010). Distribution and elimination of palladium in rats after 90-day oral administration. Toxicology and Industrial Health 26, 183-189.

ICH (2014). International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Guideline. Guideline for elemental impurities. Q3D Current Step 4 version dated 16 December 2014.

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

IPCS (2002). International Programme on Chemical Safety. Palladium. Environmental Health Criteria 226. WHO, Geneva.

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] (Wistar strain	LD50: >200 - <2000 mg/kg bw (female)	1 (reliable without

Crl(WI) BR male/female oral: gavage according to guideline OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method) ; according to guideline EU Method B.1 tris (Acute Oral Toxicity - Acute Toxic Class Method)	(CL not determined) LD50: >200 mg/kg bw (male) (CL not determined)	restriction) key study experimental study **Test material** Dihydrogen tetrachloropalladate; palladium(4+) tetrachloride / 16970-55-1 / 241-047-9, Form: liquid (full information in **Annex II**). **Reference** **van Huygevoort AHBM 2003**

5.2.1.2. Acute toxicity: inhalation

No relevant information available.

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: study scientifically not necessary / other information available

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

5.2.1.3. Acute toxicity: dermal

No relevant information available.

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: study scientifically not necessary / other information available

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

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:

Key Information:

In an OECD Test Guideline 423 study, to GLP, the acute oral LD50 value of dihydrogen tetrachloropalladate (solution) was determined to range between 200 and 2000 mg/kg bw following gavage administration in rats (van Huygevoort, 2003a).

No relevant acute dermal or inhalation toxicity data were identified. However, acute toxicity testing by a second route is not considered appropriate as dihydrogen tetrachloropalladate is considered corrosive to the skin.

Value used for CSA:
Acute oral toxicity:
adverse effect observed
(discriminating dose) 300 mg/kg bw
Acute dermal toxicity:
no study available
Acute inhalation toxicity:
no study available

Relevant studies: Acute toxicity: oral (KEY) - van Huygevoort (2003a)

Additional information:
No relevant acute toxicity human data were identified.

In an OECD Test Guideline 423 study, to GLP, dihydrogen tetrachloropalladate (solution) was studied for acute oral toxicity after single gavage administration in Wistar rats. The test substance was administered undiluted as a brown liquid at a dose of 200 mg/kg bw to both sexes (3/sex) and at 2000 mg/kg bw to 3 females. All females dosed at 2000 mg/kg bw were sacrificed due to distress on day 2 after dosing. Clinical signs included lethargy, hunched posture, uncoordinated movements, piloerection, quick breathing (lasting 1 hr after dosing) and slow breathing (on day 1). In addition, individual animals exhibited ptosis, vomiting with red spots, hypothermia, rales and laboured breathing. At 200 mg/kg bw all animals had hunched posture and rales; piloerection was observed in the females and one female also showed chromodacryorrhoea around the snout. Symptoms lasted between 1 and 7 days in females and 2 days in males. Necropsy of the females dosed at 2000 mg/kg bw showed hardening of the glandular mucosa of the stomach and a black discolouration. One female also exhibited a yellowish discolouration of the liver and a reddish, clear fluid in the abdominal cavity. No abnormal findings were evident in the animals dosed at 200 mg/kg bw that survived the observation period. The deceased male at necropsy exhibited a thickened glandular mucosa, gastro-intestinal tract distended with gas and dilation of the right kidney. Under the conditions of this test, an acute oral LD50 value for dihydrogen tetrachloropalladate solution was determined to be in the range between 200 and 2000 mg/kg bw following gavage administration in rats (van Huygevoort, 2003a). This is considered to approximate to a discriminating dose of 300 mg/kg bw. Based on the results of this acute oral rat study, dihydrogen tetrachloropalladate (solution) is classified for acute oral toxicity (category 4) according to EU CLP criteria (EC 1272/2008).

No relevant acute dermal or inhalation toxicity data were identified. However, acute toxicity testing by a second route is not considered appropriate as dihydrogen tetrachloropalladate (solution) is corrosive to the skin.

Justification for selection of acute toxicity – oral endpoint
OECD guideline study, to GLP, and the only acute oral toxicity study available

Justification for classification or non classification:
Based on the results of the available acute oral rat study, dihydrogen tetrachloropalladate (solution) is 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

No relevant information available.

5.3.1.2. Human information

No relevant information available.

5.3.2. Eye

5.3.2.1. Non-human information

No relevant information available.

Data waiving

Information requirement: Eye Irritation

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is classified as skin corrosion, leading to classification as serious eye damage (Category 1) [study scientifically not necessary / other information available] ; the study does not need to be conducted because the substance is a strong acid (pH <= 2.0) or base (pH => 11.5) and the available information indicates that it should be classified as serious eye damage (Category 1) [study scientifically not necessary / other information available]

5.3.2.2. Human information

No relevant information available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No relevant information available

5.3.3.2. Human information

No relevant information available.

5.3.4. Summary and discussion of irritation

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

Key Information:
In an in vitro membrane barrier test (CORROSITEX™ Assay), conducted according to OECD Test Guideline 435 and to GLP, dihydrogen tetrachloropalladate (solution) was considered corrosive to the skin (Lehmeier, 2013).

No relevant eye or respiratory tract irritation data were identified. However, such testing is not considered appropriate as dihydrogen tetrachloropalladate is classified as corrosive to the skin.

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

Relevant studies: Skin corrosion (KEY), CORROSITEX - Lehmeier (2013)

Additional information:
No relevant human irritation/corrosion data were identified.

In a good quality GLP study, conducted according to OECD Test Guideline 435, the potential of dihydrogen tetrachloropalladate (solution) to induce skin corrosion was assessed in the "in vitro membrane barrier test (CORROSITEX™ Assay)". The test item was placed on top of a synthetic macromolecular bio-barrier membrane which was sat on a chemical detection system (CDS) in a vial. Corrosivity is determined as the ability (measured by the time taken) of a chemical to break through the barrier and subsequently activate the underlying CDS (as seen by a colour or consistency change). The mean time required for dihydrogen tetrachloropalladate solution to activate the CDS was 2.73 minutes (mean of 4 replicates). The test substance is therefore classified as "corrosive" to the skin (category 1A), according to EU CLP criteria (EC 1272/2008), as the mean time to activate the CDS was between 0-3 minutes (Lehmeier, 2013).

No eye or respiratory tract data were identified. However, eye irritation testing is not considered appropriate as dihydrogen tetrachloropalladate(solution)is classified as corrosive to the skin.

Justification for selection of skin irritation / corrosion endpoint:
OECD guideline study, GLP compliant.

Justification for classification or non classification:
Based on the results of the available reliable in vitro skin corrosion study, dihydrogen tetrachloropalladate(solution) is classified as corrosive to the skin (category 1A) according to EU CLP criteria (EC 1272/2008). Substances that are corrosive to the skin are considered as leading to serious damage to the eyes. Consequently, dihydrogen tetrachloropalladate(solution) is classified for eye effects in Category 1 according to EU CLP criteria (EC 1272/2008).

5.4. Corrosivity

5.4.1. Non-human information

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

Table 5.2. Studies on skin irritation related to corrosivity

Method	Results	Remarks
Tissue studied: skin corrosion: in vitro / ex vivo Not applicable. (Not applicable.) according to guideline OECD Guideline 435 (In Vitro Membrane Barrier Test Method for Skin Corrosion)	Category 1A (corrosive) based on GHS criteria CORROSITEX time (minutes) mean of 4 replicates. Value: 2.73 (positive indication of irritation)	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen tetrachloropalladate; palladium(4+) tetrachloride /

		16970-55-1 / 241-047-9, Form: solution (full information in **Annex II**). **Reference** **Lehmeier D 2013**
Tissue studied: skin corrosion: in vitro / ex vivo Not applicable. (Not applicable.) according to guideline OECD Guideline 435 (In Vitro Membrane Barrier Test Method for Skin Corrosion)	Category 1B (corrosive) based on GHS criteria other: CORROSITEX time (positive indication of irritation - Basis: mean (4 replicates). Time point: 3m 43s. Remarks: Corrosive.)	1 (reliable without restriction) supporting study experimental study **Test material** Dihydrogen tetrachloropalladate (II) solution; palladium(4+) tetrachloride / 16970-55-1 / 241-047-9, Form: solution (full information in **Annex II**). **Reference** **D Lehmeier 2014**

5.4.2. Human information

No relevant information available.

5.4.3. Summary and discussion of corrosion

Skin corrosion (KEY), CORROSITEX - Lehmeier (2013)
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 5.3. Studies on skin sensitisation

Method	Results	Remarks
skin sensitisation: in vivo (non-LLNA) guinea pig (Dunkin-Hartley [guinea pig]) female Induction: intradermal and	Category 1A (indication of significant skin sensitising potential) based on GHS criteria No. with positive reactions: 1st reading : 2 out of 9 (test chemical ; 24 h after challenge;	1 (reliable without restriction) key study experimental study

epicutaneous Vehicle: water Induction: Vehicle: according to guideline OECD Guideline 406 (Skin Sensitisation) ; according to guideline EU Method B.6 (Skin Sensitisation)	dose: 5%) (Reading: 1st reading. . Hours after challenge: 24.0. Group: test group. Dose level: 5%. No with. + reactions: 2.0. Total no. in groups: 9.0. Clinical observations: body weight gains normal.) No. with positive reactions: 2nd reading : 3 out of 9 (test chemical ; 48 h after challenge; dose: 5%) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: test group. Dose level: 5%. No with. + reactions: 3.0. Total no. in groups: 9.0. Clinical observations: body weight gains normal.) No. with positive reactions: 1st reading : 0 out of 5 (negative control ; 24 h after challenge; dose: 5%) (Reading: 1st reading. . Hours after challenge: 24.0. Group: negative control. Dose level: 5%. No with. + reactions: 0.0. Total no. in groups: 5.0. Clinical observations: None.) No. with positive reactions: 2nd reading : 0 out of 5 (negative control ; 48 h after challenge; dose: 5%) (Reading: 2nd reading. . Hours after challenge: 48.0. Group: negative control. Dose level: 5%. No with. + reactions: 0.0. Total no. in groups: 5.0. Clinical observations: none.)	**Test material** Dihydrogen tetrachloropalladate; palladium(4+) tetrachloride / 16970-55-1 / 241-047-9, Form: liquid (full information in **Annex II**). **Reference** **Van Huygevoort AHBM 2003**

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

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

Table 5.4. Exposure-related observations on skin sensitisation in humans

Method	Results	Remarks
Study type: study with volunteers Type of population: general Subjects: - Number of subjects exposed: 1651 (for 3% Na2PdCl4); 1634 (for 2 and 4% Na2PdCl4) - Sex: Male and female (exact numbers not specified for the entire set of subjects; for the subset of 906 patients, 269 were male and 637 were female) - Age: For the subset of 906	NO. OF PERSONS WITH/OUT REACTIONS COMPARED TO STUDY POPULATION 2% Disodium tetrachloropalladate - Number of subjects with positive reactions: approx. 15% - Number of subjects with negative reactions: approx. 85% (equivocal and irritant reactions were regarded as negative results) - Number of subjects with equivocal	2 (reliable with restrictions) supporting study experimental study **Test material** disodium tetrachloropalladate / 13820-53-6 / 237-

patients, the mean age was 48.3 years - Race: No data - Demographic information: Patients were tested in eight European clinics: Amsterdam (n=66), Barcelona (n=118), Bari (n=90), Basle (n=175), Coimbra (n=190), Leuven (n=267), Malmo (n=353) and Odense (n=392) - Other: The subset of 906 patients from Amsterdam, Barcelona, Bari, Basle, Coimbra and Leuven had additional information on age and sex. Seventeen patients were not tested with 2% and 4% Na2PdCl4, leaving 1634 patients who were tested with these concentrations. no guideline required To determine the prevalence of hypersensitivity (patch tests) to disodium tetrachloropalladate (and other platinum group elements) among 1651 patients attending various European dermatology clinics	reactions: 72/1634 (4.4%) - Number of subjects with irritating reactions: 1/1634 (0.1%) 3% Disodium tetrachloropalladate - Number of subjects with positive reactions: 300/1651 (18.2%) - Number of subjects with negative reactions: 1351/1651 (81.8%) (equivocal and irritant reactions were regarded as negative results) - Number of subjects with equivocal reactions: 68/1651 (4.1%) - Number of subjects with irritating reactions: 1/1651 (0.1%) 4% Disodium tetrachloropalladate - Number of subjects with positive reactions: 306/1634 (18.7%) - Number of subjects with negative reactions: 1328/1634 (81.3%) (equivocal and irritant reactions were regarded as negative results) - Number of subjects with equivocal reactions: 56/1634 (3.4%) - Number of subjects with irritating reactions: 3/1634 (0.2%)	502-6, Form: not specified (full information in **Annex II**). **Reference** **Muris J, Goossens A, Gonçalo M, Bircher AJ, Giménez-Arnau A, Foti C, Bruze M, Andersen KE, Rustemeyer T, Feilzer AJ and Kleverlaan CJ 2014**

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

Key Information:
Dihydrogen tetrachloropalladate (solution) induced skin sensitisation in an OECD Test Guideline 406 GPMT, to GLP, in which a group of ten guinea pigs were dermally challenged with 5% of the test compound following a two-stage induction with 0.05% by intradermal injection and 5% applied topically (van Huygevoort, 2003b).

Value used for CSA: adverse effect observed (sensitising)

Relevant studies: Skin sensitisation, GPMT (KEY) - van Huygevoort (2003b)

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

The ability of dihydrogen tetrachloropalladate(solution)to induce contact sensitisation was assessed in a OECD Test Guideline 406 guinea pig maximisation test (GPMT), conducted to GLP, using groups of 10 test and 5 control animals. Animals were induced with 0.05% by intradermal injection, followed one week later by a second induction by topical application of 5% of the test substance under a 48-hr occlusive patch. Control

animals were similarly treated but without the test substance. A challenge dose of 5% was applied under an occlusive patch for 24 hr three weeks after topical induction to both test and control animals. These doses were selected after a preliminary range-finding study. Positive reactions were seen in 3 of the 9 animals exposed to the test substance after exposure to the challenge dose. One animal died on the day of first induction from abdominal bleeding. No reactions were observed in the control animals when examined at 24 and 48 hr after exposure to the challenge dose. No systemic toxicity was evident. Dihydrogen tetrachloropalladate(solution)induced skin sensitisation in 3 of 9 animals in the GPMT (van Huygevoort, 2003b), thus would require classification as a skin sensitiser (category 1A) according to EU CLP criteria (EC 1272/2008).

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. A new study was not conducted as no standard and validated test method is available and it is not a REACH Standard Information Requirement.

Justification for classification or non classification:
Based on the results of the available and reliable GPMT, dihydrogen tetrachloropalladate requires classification as a skin sensitiser (category 1A) 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] - Crl:WI (Wistar) rats (Rattus norvegicus)) short-term repeated dose toxicity: oral oral: feed 1000ppm target dosing level: 100 mg/kg bw/d 3000ppm target dosing level: 300 mg/kg bw/d 10000ppm	NOAEL: 272 mg/kg bw/day (actual dose received) (male/female) based on: (test mat.) body weight and weight gain ; food consumption and compound intake	1 (reliable without restriction) key study experimental study **Test material** disodium tetrachloropalladate / 13820-53-6 / 237-502-6, Form: solid:

target dosing level 1000 mg/kg bw/d Vehicle: unchanged (no vehicle) Exposure: Males were dosed for 35 days (21 days pre-mating and 14 days mating/post-mating period), then were euthanized and subjected to necropsy examination. Females were dosed for 21 days pre-mating, for up to 4 days (except one Mid dose female (#3508) where it was 15 days) mating period, through gestation (22-25 days) and up to and including the day before necropsy (at least 13 days post-partum dosing). The day of birth (when parturition was complete) was defined as Day 0 post-partum. All selected F1 offspring was terminated on Day 13 post-partum (F1 offspring selected for blood sampling was terminated on PND4 due to technical reasons and litters were culled on PND4). In order to allow for overnight fasting of dam prior necropsy on PND14, offspring was euthanized on PPD/PND13, and the dams on PPD/PND14. () according to guideline OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)		particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Szaloki N 2022**
rat [common rodent species] (Wistar [rat] - Crl:WI (Wistar) rats (Rattus norvegicus)) short-term repeated dose toxicity: oral oral: feed 1000ppm target dosing level: 100 mg/kg bw/d 3000ppm target dosing level: 300 mg/kg bw/d 10000ppm target dosing level 1000 mg/kg bw/d Vehicle: unchanged (no vehicle) Exposure: Males were dosed for 35 days (21 days pre-mating and 14 days mating/post-mating period), then were euthanized and subjected to necropsy examination. Females were dosed for 21 days pre-mating, for up to 4 days (except one Mid dose female (#3508) where it was 15 days) mating period, through gestation (22-25 days) and up to and including the day before necropsy (at least 13 days post-partum dosing). The day of birth (when parturition was complete) was defined as Day 0 post-partum. All selected F1 offspring was terminated on Day 13 post-partum (F1 offspring selected for blood sampling was terminated on PND4 due to technical reasons and litters	NOAEL: 272 mg/kg bw/day (actual dose received) (male/female) based on: (test mat.) body weight and weight gain ; food consumption and compound intake	1 (reliable without restriction) key study read-across based on grouping of substances (category approach) **Test material** Dihydrogen tetrachloropalladate, (full information in **Annex II**). **Reference** **Szaloki N 2022**

were culled on PND4). In order to allow for overnight fasting of dam prior necropsy on PND14, offspring was euthanized on PPD/PND13, and the dams on PPD/PND14. () according to guideline OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)		
Justification for type of information: Substance belongs to the group of 'tetraamminepalladate' substances. Detailed justification is added in Section 13 of IUCLID		
rat [common rodent species] (outbred albino rat (Charles River CD-1-strain)) male short-term repeated dose toxicity: oral oral: drinking water 92ppm 184ppm Vehicle: unchanged (no vehicle) Exposure: 33 days (continuous via drinkign water) no guideline followed, study predates GLP	NOAEL: >=184 ppm (male) based on: (test mat. (total fraction)) (not determinable due to absence of adverse toxic effects)	3 (not reliable) supporting study experimental study **Test material** dipotassium tetrachloropalladate / 10025-98-6 / 233-049-3, Form: not specified (full information in **Annex II**). **Reference** **Moore W, Hysell D, Hall L, Cambell K and Stara J 1975**
rat [common rodent species] (outbred albino rat (Charles River CD-1-strain)) male short-term repeated dose toxicity: oral oral: drinking water 92ppm 184ppm Vehicle: unchanged (no vehicle) Exposure: 33 days (continuous via drinkign water) no guideline followed, study predates GLP	NOAEL: >=184 ppm (male) based on: (test mat. (total fraction)) (not determinable due to absence of adverse toxic effects)	3 (not reliable) supporting study read-across based on grouping of substances (category approach) **Test material** Dihydrogen tetrachloropalladate, (full information in **Annex II**). **Reference** **Moore W, Hysell D, Hall L, Cambell K and Stara J 1975**
Justification for type of information: Substance belongs to the group of 'tetraamminepalladate' substances. Detailed justification is added in Section 13 of IUCLID		

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:
No Repeated dose toxicity data are available for dihydrogen tetrachloropalladate.
A GLP-compliant study according to OECD N°422 was performed to obtain information on the possible toxic effects of disodium tetrachloropalladate following repeated (daily) administration at a constant concentration in pelleted diet to Wistar (Crl:WI) rats at 3 dose levels (1000, 3000 and 10000 ppm test item in diet). A control group received non-treated control diet. Under the conditions of this study, the dietary administration of disodium tetrachloropalladate to Wistar rats did not result in test item related mortality. The NOAEL for systemic toxicity of the parental generation was considered to be 3000 ppm (corresponding to 272 mg/kg bw/day) based on effects on body weight, body weight gain and food consumption at 10000 ppm.
As supporting evident, the Moore et al (1975) study can be considered. The effect of K2PdCl4 was assessed in a non-guideline study during a 33-day exposure of male rats (10/group) to 92 and 184 ppm test item in drinking water. The study reports no abnormalities in general appearance, body weight and urinalysis. Although limited in experimental setup, this study can be used as supportive evidence for the generic observation of limited adverse systemic effects after repeated oral admistration of tetrachloropalladate substances.
Dihydrogen tetrachloropalladate, dipotassium tetrachloropalladate and disodium tetrachloropalladate are member of the group of ‘tetrachloropalladate’ substances, and a read-across between both substances for this endpoint is considered justified.

Considering molecular weight conversion, the NOAEL for systemic toxicity of the parental generation is 272 mg/kg bw/day disodium tetrachloropalladate or 231 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion, using the evidence from the relevant and reliable Szaloki (2022) study.

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

Toxic effect type (for all routes and effects): dose-dependent

Value used for CSA (via oral route - systemic effects):
adverse effect observed
(NOAEL: 231mg/kg bw/day; subacute, rat [common rodent species])

Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across TARGET
Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across SOURCE

Value used for CSA (inhalation - systemic effects):

no study available

Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across TARGET
Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across SOURCE

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

Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across TARGET
Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across SOURCE

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

Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across TARGET
Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across SOURCE

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

Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across TARGET
Relevant studies: Repeated dose toxicity: oral.Szaloki(2022).Read-across SOURCE

Additional information:
A GLP-compliant study according to OECD N°422 was performed to obtain information on the possible toxic effects of disodium tetrachloropalladate following repeated (daily) administration at a constant concentration in pelleted diet to Wistar (Crl:WI) rats at 3 dose levels (1000, 3000 and 10000 ppm test item in diet). A control group received non-treated control diet.
Under the conditions of this study, the dietary administration of disodium tetrachloropalladate to Wistar rats did not result in test item related mortality. The NOAEL for systemic toxicity of the parental generation was considered to be 3000 ppm (corresponding to 272 mg/kg bw/day) based on effects on body weight, body weight gain and food consumption at 10000 ppm.
Dihydrogen tetrachloropalladate and disodium tetrachloropalladate are member of the group of 'tetrachloropalladate' substances, and a read-across between both substances for this endpoint is considered justified.
Considering molecular weight conversion, the NOAEL for systemic toxicity of the parental generation is 272 mg/kg bw/day disodium tetrachloropalladate or 231 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.
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 classification or non classification:
The effects seen in the OECD422 study with disodium tetrachloropalladate are considered not sufficient to classify the substance for STOT-RE according to EU CLP criteria (EC 1272/2008). This conclusion is considered valid for dihydrogen tetrachloropalladate via a read-across approach.

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 and TA 100 [bacteria] (with and without met. act.) E. coli WP2 uvr A [bacteria] (with and without met. act.) Test concentrations: Study 1: 3, 10, 33, 100, 333, 1000, 3300 and 5000 µg/plate for TA100 and WP2 uvrA. Study 2: 3, 10, 33, 100, 200 and 333 µg/plate for TA15335, TA1537 and TA98. Study 3: 3, 10, 33, 100 and 200 µg/plate for TA15335, TA1537 and TA98 without S9; 10, 33, 100, 200 and 333 µg/plate for TA15335, TA1537 and TA98 with S9; 10, 33, 100, 200 and333 µg/plate for TA100 and WP2 uvrA with or without S9. Positive control substance(s): methylmethanesulfonate Positive control substance(s): sodium azide Positive control substance(s): 4-nitroquinoline-N-oxide Positive control substance(s): 9-aminoacridine Positive control substance(s): daunomycin Positive control substance(s): 2-aminoanthracene according to guideline OECD Guideline 471 (Bacterial Reverse Mutation Assay)	Test results: negative for S. typhimurium TA 1535 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: not specified positive controls valid: valid Test results: negative for S. typhimurium TA 1537 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: not specified positive controls valid: valid Test results: negative for S. typhimurium TA 98 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: not specified positive controls valid: valid Test results: negative for S. typhimurium TA 100 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: not specified positive controls valid: valid	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen tetrachloropalladate; palladium(4+) tetrachloride / 16970-55-1 / 241-047-9, Form: liquid (full information in **Annex II**). **Reference** **Verspeek-Rip CM 2002**

[in vitro gene mutation study in bacteria] ; according to guideline EU Method B.13/14 (Mutagenicity - Reverse Mutation Test Using Bacteria) [in vitro gene mutation study in bacteria]	Test results: negative for E. coli WP2 uvr A [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity vehicle controls valid: valid negative controls valid: not specified positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	
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: Cytotoxicity range-finder experiment: 78.22, 156.4, 312.9, 625.8, 1252 and 2503 µg/mL (both with and without S9) Experiment 1: 25, 50, 100, 150, 175, 200, 225, 250, 280, 320, 380 and 450 µg/mL (without S9) and 25, 50, 100, 150, 200, 250, 280, 320, 360, 420, 500 and 600 µg/mL (with S9) Experiment 2: 50, 100, 150, 180, 210, 240, 260, 280, 300, 350 and 400 µg/mL (without S9) and 50, 100, 150, 200, 240, 280, 320, 340, 360, 400 and 450 µg/mL (with S9) Calculation of all test article concentrations stated in this report include a correction for purity using a factor of 1.908, to allow for the Dihydrogen tetrachloropalladate (II) content of 52.41%. Positive control substance(s): 4-nitroquinoline 1-oxide (NQO; without S9) and benzo[a]pyrene (B[a]P; with S9) according to guideline 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 - Seven days after treatment, concentrations of 320-450 µg/mL (Exp 1, without S9); 420-600 µg/mL (Exp 1, with S9); 400 µg/mL (Exp 2, without S9) and 450 µg/mL (Exp 2, with S9) were considered too toxic for selection to determine viability and 6TG resistance vehicle controls valid: valid negative controls valid: not applicable positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen tetrachloropalladate; palladium(4+) tetrachloride / 16970-55-1 / 241-047-9, Form: liquid (full information in **Annex II**). **Reference** **Lloyd M 2015**
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study - Type of genotoxicity: chromosome aberration) lymphocytes: Human [primary culture] (with and without met. act.) Test concentrations: Cytotoxicity range finder experiment: 9.081, 15.13, 25.22, 42.04, 70.07, 116.8, 194.6, 324.4, 540.7, 901.1, 1502 and 2503 µg/mL (both with and without S9). Micronucleus	Test results: negative for lymphocytes: Human [primary culture]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity - concentrations of 600-750 µg/mL (3+21 hr without S9), 700-900 µg/mL (3+21 hr with S9), and 120-300 µg/mL (24+0 treatment without S9) were considered too cytotoxic for selection (i.e. RI >60%). vehicle controls valid: valid	1 (reliable without restriction) key study experimental study **Test material** Dihydrogen tetrachloropalladate (II); palladium(4+) tetrachloride / 16970-55-1 / 241-047-9,

Experiment (3+21 hr): 50, 100, 200, 300, 340, 380, 420, 450, 480, 510, 550, 600, 750 µg/mL (without S9) and 100, 200, 300, 400, 450, 500, 550, 600, 650, 700, 750, 800, 900 µg/mL (with S9). Micronucleus experiment (24+0 hr): 20, 40, 60, 80, 100, 110, 120, 130, 140, 170, 200, 300 µg/mL (without S9). Calculation of all test article concentrations stated in the study report include a correction for purity using a factor of 1.908, to allow for the Dihydrogen tetrachloropalladate (II) content of 52.41%. Positive control substance(s): cyclophosphamide ; mitomycin C ; Noscapine according to guideline OECD Test Guideline 487: In Vitro Mammalian Cell Micronucleus Test	negative controls valid: not applicable positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	Form: liquid (full information in **Annex II**). **Reference** **Lloyd M 2015**

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):
In an OECD Test Guideline 471 study, to GLP, dihydrogen tetrachloropalladate (solution) failed to induce an increase in mutation frequency in four S. typhimurium strains or in E. coli WP2 uvrA, either with or without S9, when tested at up to the limits of cytotoxicity (Verspeek-Rip, 2002).

In an OECD Test Guideline 476 study, to GLP, dihydrogen tetrachloropalladate (in solution) did not induce biologically relevant increases in mutant frequency at the hprt locus of mouse lymphoma (L5178Y) cells when tested up to cytotoxic concentrations in two independent experiments, each in the absence and presence of S9 (Lloyd, 2015a).

In an OECD Test Guideline 487 study, to GLP, dihydrogen tetrachloropalladate (in solution) failed to induce biologically significant increases in the frequency of micronuclei in cultured human peripheral blood lymphocytes when tested up to the limit of cytotoxicity for 3+21 hours in the absence and presence of S9 and for 24+0 hours in the absence of S9 (Lloyd, 2015b).

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 bacterial or 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 combined repeated dose and reproductive/developmental toxicity screening assay. As such, classification of dihydrogen tetrachloropalladate for germ cell mutagenicity is not warranted, according to EU CLP criteria (EC 1272/2008).

Relevant studies: Genetic toxicity in vitro, Ames (KEY) - Verspeek-Rip (2002)
Relevant studies: Genetic toxicity in vitro, Mouse lymphoma (KEY) - Lloyd (2015a)
Relevant studies: Genetic toxicity in vitro, human micronucleus (KEY) - Lloyd (2015b)

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

The mutagenic potential of dihydrogen tetrachloropalladate (in solution) was assessed in a reverse mutagenicity assay, conducted according to OECD Test Guideline 471 and to GLP. The test substance was assessed in four Salmonella typhimurium strains (TA1535, TA1537, TA98 and TA100) and in Escherichia coli WP2 uvrA, in an attempt to detect both base-pair substitution and frameshift mutations. In the range-finding study, dihydrogen tetrachloropalladate (in solution) was tested (in triplicate) at up to 5 mg/plate, in the presence and absence of a 5% rat liver metabolic activation (S9) system. Cytotoxicity was seen at concentrations of 0.33 mg/plate and above. In Salmonella strains TA1535, TA1537 and TA98, cytotoxicity was observed at doses of 0.2 and 0.33 mg/plate, without or with a 5% rat liver S9 respectively. In an independent repeat study using all five strains, but this time without or with a 10% S9 fraction in the S9 mix, cytotoxicity was again seen at 0.2 and 0.33 mg/plate respectively. Dihydrogen tetrachloropalladate (in solution) did not cause an increase in mutation frequency, either with or without metabolic S9 activation, when compared to the spontaneous mutation frequency. In contrast, the known mutagens used as positive controls showed the expected mutagenic activity (Verspeek-Rip, 2002).

A study was conducted to assess the potential of dihydrogen tetrachloropalladate (in solution) to induce mutations at the hprt locus of L5178Y mouse lymphoma cells. The study was undertaken in compliance with OECD Test Guideline 476 and according to GLP. Cells were exposed to test material for 3 hr in two independent experiments, each in the absence and presence of a rat liver metabolic activation system (S9). Concentrations of 25 to 450 µg/mL and 25 to 600 µg/mL (Experiment 1, without and with S9, respectively) and 50 to 400 µg/mL and 50 to 450 µg/mL (Experiment 2, without and with S9, respectively) were used. Cytotoxicity was observed seven days after treatment at the highest tested levels, with concentrations of 320-450 µg/mL (Experiment 1, without S9); 420-600 µg/mL (Experiment 1, with S9); 400 µg/mL (Experiment 2, without S9) and 450 µg/mL (Experiment 2, with S9) being considered too toxic for selection to determine viability and 6TG resistance. No statistically significant increases in mutation frequency (MF) over the concurrent vehicle control value were observed in Experiment 1 (with or without S9) or in Experiment 2 in the absence of S9. A statistically significant increase in MF was, however, seen in Experiment 2 in the presence of S9, at the highest two concentrations analysed (380 and 400 µg/mL) and at one intermediate concentration (240 µg/mL). The mean MF values at 240, 380 and 400 µg/mL were 5.35, 4.90 and 4.26 mutants/10^6 viable cells, respectively, compared to the concurrent vehicle control MF value of 1.09. These increases were small in magnitude and only statistically significant because of an unusually low vehicle control value (the historical control value was 3.17). Furthermore, there was no evidence of reproducibility between experiments in the presence of S9 (the vehicle control MF was 4.86 in Experiment 1) and no statistically significant linear trends in Experiments 1 (with or without S9) and 2 (without S9), therefore the small, non-reproducible increases seen in Experiment 2 were considered not biologically relevant. Overall, dihydrogen tetrachloropalladate (in solution) failed to induce biologically significant increases in mutation frequency at the hprt locus of L5178Y mouse lymphoma cells when tested up to cytotoxic concentrations in two independent experiments, each in the absence and presence of S9 (Lloyd, 2015a).

A study was conducted to evaluate the clastogenic and aneugenic potential of dihydrogen tetrachloropalladate (in solution) by examining its effects on the frequency of micronuclei in cultured human peripheral blood lymphocytes treated in the absence and presence of a rat liver metabolising (S9) system. The study was undertaken in compliance with OECD Test Guideline 487 and according to GLP. Treatments covering (20–900 µg/mL) a broad range of concentrations, separated by narrow intervals, were performed with and without S9. The test article was formulated in purified water. The highest concentrations tested in the micronucleus experiment were limited by toxicity and were determined following a preliminary cytotoxicity range-finder experiment. Treatments were conducted 48 hr following mitogen stimulation by PHA. The test article

concentrations for micronucleus analysis were selected by evaluating the effect of dihydrogen tetrachloropalladate (in solution) on the replication index. Micronuclei were analysed at four concentrations. Frequencies of micronucleated binucleate cells resulting from treatment with dihydrogen tetrachloropalladate (3+21 hr, with and without S9) were similar to and not significantly higher than the concurrent vehicle controls at all concentrations analysed. The frequencies under both treatment conditions were within the historical control ranges and there was no indication of a concentration-related response. Treatment of cells with dihydrogen tetrachloropalladate (24+0 hours in the absence of S9) resulted in frequencies of micronucleated binucleate (MNBN) cells that were significantly higher than the concurrent vehicle controls at 110 µg/mL (the highest concentration analysed). However, the MNBN cell frequencies of all treated cultures fell within the normal range and the small but statistically significant increase in MNBN cell frequency observed was therefore seen only at the limit of toxicity and was considered not biologically relevant. Dihydrogen tetrachloropalladate (in solution) did not induce biologically significant increases in the frequency of micronuclei in cultured human peripheral blood lymphocytes when tested up to the limit of cytotoxicity for 3+21 hours in the absence and presence of S9 and for 24+0 hours in the absence of S9 (Lloyd, 2015b).

No in vivo data were identified.

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.

5.8.3. Summary and discussion of carcinogenicity

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

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

Table 5.7. Studies on fertility

Method	Results	Remarks
rat (Wistar [rat] - Wistar Crl:WI (Wistar) rats (Rattus norvegicus)) male/female screening for reproductive / developmental toxicity oral: feed () 1000ppm target dosing level: 100 mg/kg bw/d 3000ppm target dosing level: 300 mg/kg bw/d 10000ppm target dosing level: 1000 mg/kg bw/d Vehicle: unchanged (no vehicle) Exposure: Males were dosed for 35 days (21 days pre-mating and 14 days mating/post-mating period), then were euthanized and subjected to necropsy examination. Females were dosed for 21 days pre-mating, for up to 4 days (except one Mid dose female where it was 15 days) mating period, through gestation (22-25 days) and up to and including the day before necropsy (at least 13 days post-partum dosing). The day of birth (when parturition was complete) was defined as Day 0 post-partum. All selected F1 offspring was terminated on Day 13 post-partum (F1 offspring selected for blood sampling was terminated on PND4 due to technical reasons and litters were culled on PND4). In order to allow for overnight fasting of dam prior necropsy on PND14, offspring was euthanized on PPD/PND13, and the dams on PPD/PND14. (A constant concentration of disodium tetrachloropalladate in diet were administered to all animals within a defined dosing group throughout the in-life period. Animal food consumption per cage was measured and the mean daily food intake per rat was calculated.) according to guideline OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	**First parental generation (P0)** NOAEL (PO) 272 mg/kg bw/day (actual dose received)) (male/female) based on: body weight and weight gain [general toxicity] ; food consumption and compound intake [general toxicity] (The NOAEL for reproductive effects of the parental generation was considered to be 10000 ppm (corresponding to 786 mg/kg bw/day) since no test item related adverse reproductive effects were observed.) **F1 generation** NOAEL : 272 mg/kg bw/day (actual dose received) (male/female) based on: - Effects on the mean High dose pup body weight and body weight gain were considered as secondary to maternal toxicity, as High dose females showed body weight loss during gestation and the effect on final body weights exceeded the MTD. Dam intake was >1000 mg/kg bw/day during lactation for High dose females. / **Overall reproductive toxicity** yes Lowest effective dose / concentration 272mg/kg bw/day (actual dose received) Relation to other toxic effects: reproductive effects as a secondary non-specific consequence of other toxic effects	1 (reliable without restriction) key study experimental study **Test material** disodium tetrachloropalladate / 13820-53-6 / 237-502-6, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Szaloki N 2022**
rat (Wistar [rat] - Wistar Crl:WI (Wistar) rats (Rattus norvegicus)) male/female screening for reproductive / developmental toxicity oral: feed () 1000ppm target dosing level: 100 mg/kg bw/d	**First parental generation (P0)** NOAEL (PO) 272 mg/kg bw/day (actual dose received)) (male/female) based on: body weight and weight gain [general toxicity] ; food consumption and compound intake [general toxicity] (The NOAEL for reproductive effects of the parental generation was considered	1 (reliable without restriction) key study read-across based on grouping of substances (category approach) **Test material**

3000ppm target dosing level: 300 mg/kg bw/d 10000ppm target dosing level: 1000 mg/kg bw/d Vehicle: unchanged (no vehicle) Exposure: Males were dosed for 35 days (21 days pre-mating and 14 days mating/post-mating period), then were euthanized and subjected to necropsy examination. Females were dosed for 21 days pre-mating, for up to 4 days (except one Mid dose female where it was 15 days) mating period, through gestation (22-25 days) and up to and including the day before necropsy (at least 13 days post-partum dosing). The day of birth (when parturition was complete) was defined as Day 0 post-partum. All selected F1 offspring was terminated on Day 13 post-partum (F1 offspring selected for blood sampling was terminated on PND4 due to technical reasons and litters were culled on PND4). In order to allow for overnight fasting of dam prior necropsy on PND14, offspring was euthanized on PPD/PND13, and the dams on PPD/PND14. (A constant concentration of disodium tetrachloropalladate in diet were administered to all animals within a defined dosing group throughout the in-life period. Animal food consumption per cage was measured and the mean daily food intake per rat was calculated.) according to guideline OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	to be 10000 ppm (corresponding to 786 mg/kg bw/day) since no test item related adverse reproductive effects were observed.) **F1 generation** NOAEL : 272 mg/kg bw/day (actual dose received) (male/female) based on: - Effects on the mean High dose pup body weight and body weight gain were considered as secondary to maternal toxicity, as High dose females showed body weight loss during gestation and the effect on final body weights exceeded the MTD. Dam intake was >1000 mg/kg bw/day during lactation for High dose females. / **Overall reproductive toxicity** yes Lowest effective dose / concentration 272mg/kg bw/day (actual dose received) Relation to other toxic effects: reproductive effects as a secondary non-specific consequence of other toxic effects	Dihydrogen tetrachloropalladate, (full information in **Annex II**). **Reference** **Szaloki N 2022**
Justification for type of information: Substance belongs to the group of ‘tetraamminepalladate’ substances. Detailed justification is added in Section 13 of IUCLID		

Toxicity to reproduction: other studies

No relevant information available.

5.9.1.2. Human information

No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

No relevant information available.

5.9.2.2. Human information

No relevant information available.

5.9.3. Summary and discussion of reproductive toxicity

Toxic effect type (for all routes and effects - fertility / developmental toxicity): dose-dependent

Effects on fertility

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

No experimental data are available for dihydrogen tetrachloropalladate for this endpoint.
A GLP-compliant study according to OECD N°422 was performed to obtain information on the possible effects on toxicity and reproductive performance of disodium tetrachloropalladate following repeated (daily) administration at a constant concentration in pelleted diet to Wistar (Crl:WI) rats at 3 dose levels (1000, 3000 and 10000 ppm test item in diet). A control group received non-treated control diet.
Under the conditions of this study, the dietary administration of disodium tetrachloropalladate to Wistar rats did not result in test item related mortality.
The NOAEL for systemic toxicity of the parental generation was considered to be 3000 ppm (corresponding to 272 mg/kg bw/day) based on effects on body weight, body weight gain and food consumption at 10000 ppm.
The NOAEL for reproductive effects of the parental generation was considered to be 10000 ppm (corresponding to 786 mg/kg bw/day) based on no test item related adverse reproductive effects.
The NOAEL for pup development and survival was considered to be 3000 ppm (corresponding to 272 mg/kg bw/day). Effects on the mean High dose pup body weight and body weight gain were considered as secondary to maternal toxicity, as High dose females showed body weight loss during gestation and the effect on final body weights exceeded the MTD. Dam intake was >1000 mg/kg bw/day during lactation for High dose females.
Dihydrogen tetrachloropalladate and disodium tetrachloropalladate are member of the group of 'tetrachloropalladate' substances, and a read-across between both substances for this endpoint is considered justified.
Considering molecular weight conversion:
-NOAEL for systemic toxicity of the parental generation is 272 mg/kg bw/day disodium tetrachloropalladate or 231 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.
-NOAEL for reproductive effects of the parental generation is 786 mg/kg bw/day disodium tetrachloropalladate or 669 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.
-NOAEL for pup development and survival is 272 mg/kg bw/day disodium tetrachloropalladate or 231 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.

Value used for CSA (route: oral):
no adverse effect observed (NOAEL): 669mg/kg bw/day (subacute, rat [common rodent species])

Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across TARGET
Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across SOURCE

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

Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across TARGET
Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across SOURCE

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

Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across TARGET

Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across SOURCE

Additional information:
No experimental data are available for dihydrogen tetrachloropalladate for this endpoint.
A GLP-compliant study according to OECD N°422 was performed to obtain information on the possible effects on toxicity and reproductive performance of disodium tetrachloropalladate following repeated (daily) administration at a constant concentration in pelleted diet to Wistar (Crl:WI) rats at 3 dose levels (1000, 3000 and 10000 ppm test item in diet). A control group received non-treated control diet.
Under the conditions of this study, the dietary administration of disodium tetrachloropalladate to Wistar rats did not result in test item related mortality.
The NOAEL for systemic toxicity of the parental generation was considered to be 3000 ppm (corresponding to 272 mg/kg bw/day) based on effects on body weight, body weight gain and food consumption at 10000 ppm.
The NOAEL for reproductive effects of the parental generation was considered to be 10000 ppm (corresponding to 786 mg/kg bw/day) based on no test item related adverse reproductive effects.
The NOAEL for pup development and survival was considered to be 3000 ppm (corresponding to 272 mg/kg bw/day). Effects on the mean High dose pup body weight and body weight gain were considered as secondary to maternal toxicity, as High dose females showed body weight loss during gestation and the effect on final body weights exceeded the MTD. Dam intake was >1000 mg/kg bw/day during lactation for High dose females.
Dihydrogen tetrachloropalladate and disodium tetrachloropalladate are member of the group of 'tetrachloropalladate' substances, and a read-across between both substances for this endpoint is considered justified.
Considering molecular weight conversion:
-NOAEL for systemic toxicity of the parental generation is 272 mg/kg bw/day disodium tetrachloropalladate or 231 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.
-NOAEL for reproductive effects of the parental generation is 786 mg/kg bw/day disodium tetrachloropalladate or 669 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.
-NOAEL for pup development and survival is 272 mg/kg bw/day disodium tetrachloropalladate or 231 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.

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

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

Developmental toxicity

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

No experimental data are available for dihydrogen tetrachloropalladate for this endpoint.
A GLP-compliant study according to OECD N°422 was performed to obtain information on the possible effects on toxicity and reproductive performance of disodium tetrachloropalladate following repeated (daily) administration at a constant concentration in pelleted diet to Wistar (Crl:WI) rats at 3 dose levels (1000, 3000 and 10000 ppm test item in diet). A control group received non-treated control diet.
Under the conditions of this study, the dietary administration of disodium tetrachloropalladate to Wistar rats did not result in test item related mortality.
The NOAEL for systemic toxicity of the parental generation was considered to be 3000 ppm (corresponding to 272 mg/kg bw/day) based on effects on body weight, body weight gain and food consumption at 10000 ppm.
The NOAEL for reproductive effects of the parental generation was considered to be 10000 ppm (corresponding to 786 mg/kg bw/day) based on no test item related adverse reproductive effects.
The NOAEL for pup development and survival was considered to be 3000 ppm (corresponding to 272 mg/kg bw/day). Effects on the mean High dose pup body weight and body weight gain were considered as secondary to maternal toxicity, as High dose females showed body weight loss during gestation and the effect on final body weights exceeded the MTD. Dam intake was >1000 mg/kg bw/day during lactation for High dose females.
Dihydrogen tetrachloropalladate and disodium tetrachloropalladate are member of the group of 'tetrachloropalladate' substances, and a read-across between both substances for this endpoint is considered justified.

Considering molecular weight conversion:
-NOAEL for systemic toxicity of the parental generation is 272 mg/kg bw/day disodium tetrachloropalladate or 231 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.
-NOAEL for reproductive effects of the parental generation is 786 mg/kg bw/day disodium tetrachloropalladate or 669 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.
-NOAEL for pup development and survival is 272 mg/kg bw/day disodium tetrachloropalladate or 231 mg/kg bw/d dihydrogen tetrachloropalladate using molecular weight conversion.

Effect on developmental toxicity - development (via oral route)

Value used for CSA (route: oral):
no adverse effect observed (NOAEL): 231mg/kg bw/day (subacute; rat [common rodent species])

Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across TARGET
Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across SOURCE

Effect on developmental toxicity - development (via dermal route)

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

Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across TARGET
Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across SOURCE

Effect on developmental toxicity - development (via inhalation route)

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

Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across TARGET
Relevant studies: Toxicity to reproduction.Szaloki(2022).Read-across SOURCE

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

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

Justification for classification or non classification:
Reproductive effects observed in an OECD 422 are secondary non-specific consequence of maternal toxic effects (effects exceeded the MTD and substance intake of dams was >1000 mg/kg bw/day during lactation). Therefore, effects seen in the OECD422 study with disodium tetrachloropalladate are considered not sufficient to classify the substance for reproductive toxicity according to EU CLP criteria (EC 1272/2008). Based on a justified read-across approach, the same conclusion is taken for dihydrogen tetrachloropalladate.

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

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No relevant information available.

5.10.1.2. Immunotoxicity

No relevant information available.

5.10.1.3. Specific investigations: other studies

No relevant information available.

5.10.1.4. Additional toxicological effects

No relevant information available.

5.10.2. Human information

No relevant information available.

5.10.3. Summary and discussion of other effects

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

5.11.1. Overview of typical dose descriptors for all endpoints

Table 5.8. 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 (discriminating dose):
Acute toxicity	dermal	no study available
Acute toxicity	inhalation	no study available
Irritation / Corrosivity	skin	adverse effect observed (corrosive)
Irritation / Corrosivity	eye	no study available
Irritation / Corrosivity	resp. tract	no study available
Sensitisation	skin	adverse effect observed (sensitising)
Sensitisation	resp. tract	no study available
Repeated dose toxicity	oral	adverse effect observed (NOAEL): 231mg/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): 669mg/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): 231mg/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 5.9. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 10.9mg/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) 3.1mg/kg bw/day	repeated dose toxicity (Oral)
Dermal	Systemic effects - Acute	no hazard identified	

Dermal	Local effects - Long-term	high hazard (no threshold derived)	sensitisation (skin)
Dermal	Local effects - Acute	high 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; NOAEL from a well-conducted combined repeated dose and reproductive/developmental toxicity study; the dietary levels were set with the aim of achieving a dose of 1000 mg/kg bw/day in the high dose group, though this was around 786.1 mg/kg bw/day in reality)

AF for difference in duration of exposure: 6 (Default ECHA AF for subacute (28-day) to chronic extrapolation. Male animals were dosed for 28-days in total, while low- and mid-dose females received treatment for a longer period of time (cfr. OECD422 guideline))

AF for interspecies differences (allometric scaling): 1 (Default ECHA AF of 4 for rat for toxicokinetic differences in metabolic rate (allometric scaling) is not required)

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

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

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

AF for remaining uncertainties: 1 (Not required)

Further explanation on hazard conclusions:

See discussion section (Hazard via 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; NOAEL from a well-conducted combined repeated dose and reproductive/developmental toxicity study; the dietary levels were set with the aim of achieving a dose of 1000 mg/kg bw/day in the high dose group, though this was around 786.1 mg/kg bw/day in reality)

AF for difference in duration of exposure: 6 (Default ECHA AF for subacute (28-day) to chronic extrapolation. Male animals were dosed for 28-days in total, while low- and mid-dose females received treatment for a longer period of time (cfr. OECD422 guideline))

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.)

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 dihydrogen tetrachloropalladate in humans or laboratory animals are available, route-to-route extrapolation to calculate an inhalation DNEL from a combined repeated dose and reproductive/developmental oral toxicity study on disodium tetrachloropalladate, a substance that was

considered to fall in the same category of tetrachloropalladate substances. Data for category member substances are considered equally applicable amongst each other and thus a suitable alternative for category member substances without substance specific data..
A GLP-compliant repeated dose toxicity study combined with reproductive toxicity screening (according to OECD422) with disodium tetrachloropalladate is available (Szaloki, 2022). This study is used as basis for route-to-route extrapolation to calculate an inhalation DNEL.
The oral NOAEL for disodium tetrachloropalladate is 272 mg/kg(bw)/day. This value is protective against systemic effect, reproductive effects and effects on pup development and growth. Via molecular weight conversion, the corresponding value for dihydrogen tetrachloropalladate is 231 mg/kg(bw)/d.
In the absence of data allowing quantitative comparison between absorption following oral and inhalation exposure, this derivation utilised the REACH 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)
= 231 mg/kg bw/day*(1/0.38 m³/kg bw/day)*(1/2)*(6.7 m³ [8h]/10 m³ [8h]) =203.7 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 = 203.7*4 = 814.5 mg/m³.

Justification and comments
No relevant data on effects of repeated exposure to dihydrogen tetrachloropalladate in humans or laboratory animals are available. Disodium tetrachloropalladate is considered to fall in the same category of tetrachloropalladate substances. Data for category member substances are considered equally applicable amongst each other and thus a suitable alternative for category member substances without substance specific data.
A GLP-compliant study according to OECD N°422 was performed to obtain information on the possible effects on toxicity and reproductive performance of disodium tetrachloropalladate following repeated (daily) administration at a constant concentration in pelleted diet to Wistar (Crl:WI) rats at 3 dose levels (1000, 3000 and 10000 ppm test item in diet). A control group received non-treated control diet.
Under the conditions of this study, the dietary administration of disodium tetrachloropalladate to Wistar rats did not result in test item related mortality.
The NOAEL for systemic toxicity of the parental generation was 3000 ppm (corresponding to 272 mg/kg bw/day) based on effects on body weight, body weight gain and food consumption at 10000 ppm. Using molecular weight conversion, the corresponding NOAEL for dihydrogen tetrachloropalladate is 231 mg/kg(bw)/day.
The NOAEL for reproductive effects of the parental generation 10000 ppm (corresponding to 786 mg/kg bw/day) based on no test item related adverse reproductive effects. Using molecular weight conversion, the corresponding NOAEL for dihydrogen tetrachloropalladate is 668 mg/kg(bw)/day.
The NOAEL for pup development and survival was 3000 ppm (corresponding to 272 mg/kg bw/day). Effects on the mean High dose pup body weight and body weight gain were considered as secondary to maternal toxicity, as High dose females showed body weight loss during gestation and the effect on final body weights exceeded the MTD. Dam intake was >1000 mg/kg bw/day during lactation for High dose females. Using molecular weight conversion, the corresponding NOAEL for dihydrogen tetrachloropalladate is 231 mg/kg(bw)/day.
Considering the outcome of this assay, the use of a NOAEL = 272 mg/kg(bw)/d is considered suitably protective of systemic and reproductive effects.
Hence, the NOAEL of 272 mg/kg bw/day was taken as the critical point of departure for calculating the long-term systemic DNELs for disodium tetrachloropalladate and is considered protective. Using molecular weight

conversion, the corresponding NOAEL for dihydrogen tetrachloropalladate is 231 mg/kg(bw)/day.

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 dihydrogen tetrachloropalladate. In a guideline (OECD TG 401) acute oral toxicity study in rats with dihydrogen tetrachloropalladate, the LD50 value was determined to lie between 200 and 2000 mg/kg bw (van Huygevoort, 2003a). The compound is classified in Category 4 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".

As the substance is marketed or used in a non solid or granular form, inhalation is not considered to be a significant route of exposure.

Further, given that the long-term systemic inhalation DNEL is high (above 10 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 10 mg/m³ as these would not be tolerated in the workplaces (due to the general standards applicable to control of particulates). Long-term DNELs for systemic effects are expected to be sufficient to ensure that adverse effects do not occur. 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, dihydrogen tetrachloropalladate is classified in Category 4, 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-DNELs for respiratory tract irritation/corrosion or sensitisation have been calculated. However, according to ECHA (2012b) guidance (Part E), "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".

Dihydrogen tetrachloropalladate is classified as a strong skin sensitiser (category 1A). 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".

Dihydrogen tetrachloropalladate is classified as a strong skin sensitiser (category 1A). 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 dihydrogen tetrachloropalladate in humans or laboratory animals are available, route-to-route extrapolation to calculate an inhalation DNEL from a combined repeated dose and reproductive/developmental oral toxicity study on disodium tetrachloropalladate, a substance that was considered to fall in the same category of tetrachloropalladate substances. Data for category member substances are considered equally applicable amongst each other and thus a suitable alternative for category member substances without substance specific data..

A GLP-compliant repeated dose toxicity study combined with reproductive toxicity screening (according to OECD422) with disodium tetrachloropalladate is available (Szaloki, 2022). This study is used as basis for route-to-route extrapolation to calculate an inhalation DNEL.

The oral NOAEL for disodium tetrachloropalladate is 272 mg/kg(bw)/day. This value is protective against systemic effect, reproductive effects and effects on pup development and growth. Via molecular weight conversion, the corresponding value for dihydrogen tetrachloropalladate is 231 mg/kg(bw)/d.

Dihydrogen tetrachloropalladate, with water solubility in excess of 10,000 mg/L (Gregory, 2014), may be unable to cross the lipid-rich environment of the stratum corneum. However, based on a mean breakthrough time of about 3 minutes in an in vitro membrane barrier test (BSL Bioservice, 2013), the compound is classified as corrosive sub-category 1A. This corrosive 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

No relevant data on effects of repeated exposure to dihydrogen tetrachloropalladate in humans or laboratory animals are available. Disodium tetrachloropalladate is considered to fall in the same category of tetrachloropalladate substances. Data for category member substances are considered equally applicable amongst each other and thus a suitable alternative for category member substances without substance specific data

A GLP-compliant study according to OECD N°422 was performed to obtain information on the possible effects on toxicity and reproductive performance of disodium tetrachloropalladate following repeated (daily) administration at a constant concentration in pelleted diet to Wistar (Crl:WI) rats at 3 dose levels (1000, 3000 and 10000 ppm test item in diet). A control group received non-treated control diet.

Under the conditions of this study, the dietary administration of disodium tetrachloropalladate to Wistar rats did not result in test item related mortality.

The NOAEL for systemic toxicity of the parental generation was 3000 ppm (corresponding to 272 mg/kg bw/day) based on effects on body weight, body weight gain and food consumption at 10000 ppm. Using molecular weight conversion, the corresponding NOAEL for dihydrogen tetrachloropalladate is 231 mg/kg(bw)/day.

The NOAEL for reproductive effects of the parental generation 10000 ppm (corresponding to 786 mg/kg bw/day) based on no test item related adverse reproductive effects. Using molecular weight conversion, the corresponding NOAEL for dihydrogen tetrachloropalladate is 668 mg/kg(bw)/day.

The NOAEL for pup development and survival was 3000 ppm (corresponding to 272 mg/kg bw/day). Effects on the mean High dose pup body weight and body weight gain were considered as secondary to maternal toxicity, as High dose females showed body weight loss during gestation and the effect on final body weights exceeded the MTD. Dam intake was >1000 mg/kg bw/day during lactation for High dose females. Using molecular weight conversion, the corresponding NOAEL for dihydrogen tetrachloropalladate is 231 mg/kg(bw)/day.

Considering the outcome of this assay, the use of a NOAEL = 272 mg/kg(bw)/d is considered suitably protective of systemic and reproductive effects.

Hence, the NOAEL of 272 mg/kg bw/day was taken as the critical point of departure for calculating the long-term systemic DNELs for disodium tetrachloropalladate and is considered protective. Using molecular weight conversion, the corresponding NOAEL for dihydrogen tetrachloropalladate is 231 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. In a guideline (OECD TG 401) acute oral toxicity study in rats with dihydrogen tetrachloropalladate, the LD50 value was determined to lie between 200 and 2000 mg/kg bw (van Huygevoort, 2003a). The compound is classified in Category 4 according to CLP criteria.
The long-term systemic dermal DNEL is 3.1 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".
The foreseeable industrial situations are highly unlikely to result in peak exposures well above 3.1 mg/kg bw/day due to the general standards applicable to control.
Long-term DNELs for systemic effects are expected to be sufficient to ensure that adverse effects do not occur. 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, dihydrogen tetrachloropalladate is classified in Category 4, 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 435) in vitro membrane barrier test, dihydrogen tetrachloropalladate was classified as corrosive sub-category 1A under GHS, on the basis of a mean breakthrough time of about 3 minutes (Lehmeier, 2013). 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 high hazard band according to ECHA (2012b) guidance.
In another guideline (OECD TG 406) study, dihydrogen tetrachloropalladate induced skin sensitisation in the guinea pig maximisation test (GPMT). Evidence of sensitisation was observed in >30% of the treated animals, after induction by intradermal injection (0.05%; a second induction, by topical application at 5%, occurred one week later) and a challenge concentration of 5% applied three weeks later (van Huygevoort, 2003b). The compound is classified for skin sensitisation as Category 1A, under CLP.
According to ECHA (2012b) guidance "strong skin sensitizers (classified in Sub-category 1A in CLP) are allocated to the high hazard band on the basis that exposure to such potent skin sensitising substances should be strictly contained and dermal contact avoided". Further, "substances classified as Skin corrosive Category 1A according to CLP, which relates to strong corrosive effects, are allocated to the high hazard band on the basis that exposure to such extreme corrosive substances should be strictly contained".
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 435) in vitro membrane barrier test, dihydrogen tetrachloropalladate was classified as corrosive sub-category 1A under GHS, on the basis of a mean breakthrough time of about 3 minutes (Lehmeier, 2013). 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 high hazard band according to ECHA (2012b) guidance.
In another guideline (OECD TG 406) study, dihydrogen tetrachloropalladate induced skin sensitisation in the GPMT. Evidence of sensitisation was observed in >30% of the treated animals (van Huygevoort, 2003b). The compound is classified for skin sensitisation as Category 1A, under CLP.
According to ECHA (2012b) guidance "strong skin sensitizers (classified in Sub-category 1A in CLP) are allocated to the high hazard band on the basis that exposure to such potent skin sensitising substances should be strictly contained and dermal contact avoided". Further, "substances classified as Skin corrosive Category 1A according to CLP, which relates to strong corrosive effects, are allocated to the high hazard band on the basis that exposure to such extreme corrosive substances should be strictly contained".
Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

Hazard for the eyes
Justification and comments

According to ECHA guidance on the application of CLP criteria (ECHA, 2015), “if a substance or mixture is classified as Skin corrosive Category 1 then serious damage to eyes is implicit and there is no need to proceed with classification for eye effects”. Dihydrogen tetrachloropalladate is classified for skin effects as corrosive sub-category 1A. Consequently, the compound is classified for eye effects in Category 1 under EU CLP.
No dose-response data was available from which to derive a DNEL, therefore a qualitative assessment was considered appropriate. Substances classified for serious eye damage (Category 1 in CLP) should be allocated to the “moderate hazard band on the basis that exposure to such corrosives, eye damaging or irritant substances should be well-controlled”. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2012b).

Table 5.10. 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 dihydrogen tetrachloropalladate, no uses have been identified in which consumers are exposed to dihydrogen tetrachloropalladate. In all uses with potential consumer exposure due to service life of articles, dihydrogen tetrachloropalladate is chemically transformed into another substance before reaching the consumers, and the subsequent lifecycle steps after this transformation of dihydrogen tetrachloropalladate 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 dihydrogen tetrachloropalladate 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: Dihydrogen tetrachloropalladate (2-)

Related composition: dihydrogen tetrachloropalladate(2-) (Solution)

Classification: data conclusive but not sufficient for classification

6.2. Flammability

Flammability

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

Flash Point

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

Table 6.1. Information on flash point

<table>
<tr><th>Method</th><th>Results</th><th>Remarks</th></tr>
<tr><td>Determination of flash point equilibrium method closed cup according to guideline EU Method A.9 (Flash-Point)</td><td>Flash point:
(no flash point - measurement carried out until boiling temperature - No flashpoint was observed up to 120°C. Afterwards boiling was observed.)
Remarks:
Table 1: Preliminary test
<table>
<tr><th>Test item / mL</th><th>Starting temperature / °C</th><th>Heating / °C/min</th><th>Final temperature / °C</th><th>Ignition + / -</th></tr>
<tr><td>2</td><td>10</td><td>5</td><td>130 *</td><td>-</td></tr>
<tr><td>4</td><td>100</td><td>5</td><td>120</td><td>-</td></tr>
</table>
* At a temperature of 100°C, 2 mL of test item were added.</td><td>1 (reliable without restriction)
key study
experimental study

Test material
Dihydrogen tetrachloropalladate(II) solution,
Form: aqueous solution (full information in Annex II).

Reference
Nau M. 2017</td></tr>
</table>

Discussion

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

Key Information:
No flashpoint was observed for dihydrogen tetrachloropalladate up to 120°C. Afterwards boiling was observed.

Relevant studies: Flash point. Nau 2017

Additional information:
Nau (2017) is a GLP-compliant study following EU method A9. It is considered suitable for use as the key study for this endpoint. No flashpoint was observed for dihydrogen tetrachloropalladate up to 120°C. Afterwards boiling was observed.

Classification according to GHS

Name: Dihydrogen tetrachloropalladate (2-)

Related composition: dihydrogen tetrachloropalladate(2-) (Solution)

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

6.3. Oxidising potential

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

Classification according to GHS

Name: Dihydrogen tetrachloropalladate (2-)

Related composition: dihydrogen tetrachloropalladate(2-) (Solution)

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

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

7.1.1. Fish

7.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

Table 7.1. Short-term effects on fish

Method	Results	Remarks
Oncorhynchus mykiss (previous name: Salmo gairdneri) freshwater short-term toxicity to fish according to guideline OECD Guideline 203 (Fish, Acute Toxicity Test)	LC50 (96h): 154 µg/L element - palladium (meas. (geom. mean)) based on: mortality (fish) (95% CL 102 - 223) LC50 (96h): 306 µg/L test mat. - diamminedichloropalladium (meas. (geom. mean)) based on: mortality (fish) (95% CL 203 - 443) LC10 (96h): 180 µg/L test mat. - diamminedichloropalladium (meas. (geom. mean)) based on: mortality (fish) LC10 (96h): 90.4 µg/L element - palladium (meas. (geom. mean)) based on: mortality (fish)	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 guideline OECD Guideline 203 (Fish, Acute Toxicity Test)	LC50 (96h): 0.191 mg/L element - palladium (nominal) based on: mortality (fish) (Concentration expressed as palladium, determined based on molecular weight coversion) LC50 (96h): 0.53 mg/L test mat. (nominal) based on: mortality (fish) (95% Confidence Limits of 0.44-0.64 mg/l) NOEC (96h): >=0.32 mg/L test mat. (nominal) based on: mortality (fish)	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 guideline 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 guideline 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): 0.0214 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 guideline 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 guideline 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 guideline 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) NOEC (21d): 42.7 µg/L element (dissolved fraction) - Pd (meas. (TWA)) based on:	1 (reliable without restriction) key study experimental study **Test material** Tetraamminepalladi

	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)	um (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
Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum) [green algae] (algae) freshwater toxicity to aquatic algae and cyanobacteria according to guideline 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 - 4.45) EC10 (72h): 1.43 µg/L element - Palladium	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**

	(meas. (geom. mean)) based on: yield (95% CL 1.26 - 1.59)	
Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) [green algae] (algae) freshwater toxicity to aquatic algae and cyanobacteria according to guideline EU Method C.3 (Algal Inhibition test) ; according to guideline 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 [green algae] (algae) freshwater toxicity to aquatic algae and cyanobacteria equivalent or similar to guideline 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 [green algae] (algae) freshwater toxicity to aquatic algae and cyanobacteria equivalent or similar to guideline 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) [green algae] (algae) freshwater toxicity to aquatic algae and cyanobacteria according to guideline 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**
Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum) [green algae] (algae) freshwater toxicity to aquatic algae and cyanobacteria according to guideline 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 guideline 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 on: emergence rate - development rate and development time (95% CL: not	1 (reliable without restriction) key study experimental study **Test material** 14323-43-4 / 238-269-3; Diamminedichloropalladium (II), Form: solid: particulate/powder -

	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)	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 guideline 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 guideline 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 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:	3 (not reliable) supporting study experimental study **Test material** palladium(2+) dichloride / 7647-10-1 / 231-596-2, Form: solution (full information in **Annex II**).

	reproduction	**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 guideline OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to guideline EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition Test)	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 domestic sewage freshwater static according to guideline OECD Guideline 209 (Activated Sludge, Respiration	EC10 (3h): 5260 µg/L element (nominal) based on: inhibition of total respiration - respiration rate EC50 (30min): >100 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate	2 (reliable with restrictions) key study experimental study **Test material**

Inhibition Test [before 22 July 2010]	EC50 (3h): 35 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate	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 guideline OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to guideline EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition Test)	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	Assessment factor: 50 Extrapolation method: assessment factor

	Intermittent releases:	PNEC aqua (freshwater) cfr. PNEC derivation report (IUCLID Section 13)
Marine water	PNEC aqua (marine water): 0.0045µg/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): 0.0274mg/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: 0.0197mg/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
Tetraamminepalladium(2+) dichloride	H8Cl2N4Pd	241.4	44.1	8.1	5.1	category Acute 1	M=100	category Chronic 1	M=10
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
Diammon	(NH4)2P	355.2	30.0	11.9	7.5	category	M=10	category	M=10

ium hexachloropalladate	dCl6					Acute 1		Chronic 1	
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:
Dihydrogen tetrachloropalladate(2-). 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 3.7.

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
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
Dihydrogen tetrachloropalladate for OCC assessment	• 100% Dihydrogen tetrachloropalladate(2-)	**Relevant for the assessment of contributing scenarios for:** - Workers/Consumers **Method for calculating the RCR across the AEs:** Summed RCR

9.0.3. Introduction to the assessment for the environment

9.0.3.1. Tonnage

Assessed tonnage: 28 tonnes/year based on:
- 28 tonnes/year manufactured

Tonnage supplied per market sector:

Manufacture of other substances: 28 tonnes/year
Treatment of surfaces: 28 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)	28		
	- Manufacture of the substance (as such) ES 1.1 (ERC 1)		0.1	28
	- Manufacture of the substance (as such) ES 1.2 (ERC 1)		0.1	28

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)
	- Manufacture of the substance (as such) ES 1.3 (ERC 1)		1.8E-3	0.5
ES2 (IS)	Use as an intermediate	28		
	- Use as an intermediate ES 2.1 (ERC 6a)		0.1	28
	- Use as an intermediate ES 2.2 (ERC 6a)		0.1	28
	- Use as an intermediate ES 2.3 (ERC 6a)		1.8E-3	0.5
ES3 (IS)	Use as an intermediate in the catalyst industry	28		
	- Use as an intermediate in the catalyst industry (ERC 6a)		0.023	6.5
ES4 (F)	Formulation	28		
	- Formulation (ERC 2)		7.86E-3	2.2
ES5 (IS)	Use in metal surface treatment	28		
	- Use in metal surface treatment (ERC 5)		3.27E-3	0.72
ES6 (SL)	Service life of treated articles			
	- Service life of treated articles (ERC 10a)		-	-

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 used for the assessment	106.4
Melting point at 101 325 Pa	-70.7 °C
Vapour pressure	1E-12 Pa at 20 °C
Water solubility	10 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	Dihydrogen tetrachloropalladate(2-)	Quantitative	DNEL (Derived No Effect Level) = 10.9 mg/m³
	Systemic effects - acute	Dihydrogen tetrachloropalladate(2-)	Not needed	No hazard identified
	Local effects - long term	Dihydrogen tetrachloropalladate(2-)	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	Dihydrogen tetrachloropalladate(2-)	Qualitative	Medium hazard (no threshold derived)
Dermal	Systemic effects - long term	Dihydrogen tetrachloropalladate(2-)	Quantitative	DNEL (Derived No Effect Level) = 3.1 mg/kg bw/day
	Systemic effects - acute	Dihydrogen tetrachloropalladate(2-)	Not needed	No hazard identified
	Local effects - long term	Dihydrogen tetrachloropalladate(2-)	Qualitative	High hazard (no threshold derived)
	Local effects - acute	Dihydrogen tetrachloropalladate(2-)	Qualitative	High hazard (no threshold derived)
Eye	Local effects	Dihydrogen tetrachloropalladate(2-)	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	Fully contained processes	PROC 1
CS 5	Wet chemistry in open or semi-closed processes	PROC 4
CS 6	Handling/Transfer of solutions	PROC 8b
CS 7	Small scale handling/transfer of solutions	PROC 9
CS 8	Wet cleaning	PROC 8a

Further description of the use:

Dihydrogen tetrachloropalladate is produced by dissolving PdCl2 in Hydrochloric acid solution, followed by filtration of insoluble parts. Material is only stable in hydrochloric acid solution.

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: <= 28 tonnes/year *65.8 tonnes dihydrogen tetrachloropalladate (28.0 tonnes Pd metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.1 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 9.7. 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:** 5.62E-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:** 3E-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 9.8. 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:** 1.52E-5 mg/L RCR = 0.338	Final RCR = 0.338
Sediment (freshwater)	Pd dissolved	**Local PEC:** 0.037 mg/kg dw RCR = 0.136	Final RCR = 0.136
Sewage Treatment Plant	Pd dissolved	**Local PEC:** 4.98E-4 mg/L RCR = 9.47E-4	Final RCR < 0.01
Agricultural soil	Pd dissolved	**Local PEC:** 2.13E-3 mg/kg dw RCR = 0.108	Final RCR = 0.108

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: <= 28 tonnes/year *65.8 tonnes dihydrogen tetrachloropalladate (28.0 tonnes Pd metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.1 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 9.9. 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:** 5.62E-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:** 3E-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 9.10. 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-6 mg/L RCR = 0.044	Final RCR = 0.044
Sediment (freshwater)	Pd dissolved	**Local PEC:** 4.9E-3 mg/kg dw RCR = 0.018	Final RCR = 0.018
Agricultural soil	Pd dissolved	**Local PEC:** 2.13E-3 mg/kg dw RCR = 0.108	Final RCR = 0.108

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 *1.18 tonnes dihydrogen tetrachloropalladate (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 9.11. 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.

9.1.3.3. 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 9.12. 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: Fully contained processes (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate 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: Very low	MEASE 1
• Physical form of the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Maximum process temperature: 120 °C	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1

	Method
• Level of containment: Closed process	MEASE 1
• Pattern of use: Closed system without breaches	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.1.4.2. Exposure and risks for workers

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

Table 9.13. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	1 µg/m³ (MEASE 1) RCR = 9.17E-5	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	1.71 µg/kg bw/day (MEASE 1) RCR = 5.52E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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: Wet chemistry in open or semi-closed processes (PROC 4)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.1.5.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Maximum process temperature: 50 °C	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
• 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
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.1.5.2. Exposure and risks for workers

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

Table 9.14. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	11 µg/m³ (MEASE 1) RCR = 1.01E-3	Final RCR < 0.01

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	0.34 µg/kg bw/day (MEASE 1) RCR = 1.1E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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: Handling/Transfer of solutions (PROC 8b)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate 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: Very low	MEASE 1
• Physical form of the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
• 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
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.1.6.2. Exposure and risks for workers

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

Table 9.15. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	2 µg/m³ (MEASE 1) RCR = 1.83E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	0.34 µg/kg bw/day (MEASE 1) RCR = 1.1E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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: Small scale handling/transfer of solutions (PROC 9)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.1.7.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1

	Method
• Maximum emission potential of the substance: Very low	MEASE 1
• Physical form of the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] Inhalation explanation: *Efficiency for industrial use*	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
• 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
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.1.7.2. Exposure and risks for workers

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

Table 9.16. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Assessment entity**	**Exposure concentration**	**Risk quantification**
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	2 µg/m³ (MEASE 1) RCR = 1.83E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	3.43 µg/kg bw/day (MEASE 1) RCR = 1.11E-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 Dihydrogen tetrachloropalladate(2-):
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: Wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.1.8.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Immediate removal of splashes: Splashes should be removed immediately before drying of the substance	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
• 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	MEASE 1

	Method
earlier. [Effectiveness Dermal: 90%]	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.1.8.2. Exposure and risks for workers

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

Table 9.17. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	50 µg/m³ (MEASE 1) RCR = 4.59E-3	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011
Combined routes, systemic, long-term			Final RCR = 0.016

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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); SU 9: Manufacture of fine chemicals; SU 14: Manufacture of basic metals, including alloys

Environment contributing scenario(s):		
CS 1	Use as an intermediate ES 2.1	ERC 6a
CS 2	Use as an intermediate ES 2.2	ERC 6a
CS 3	Use as an intermediate ES 2.3	ERC 6a
Worker contributing scenario(s):		
CS 4	Handling/Transfer of solutions	PROC 8b
CS 5	Small scale handling/transfer of solutions	PROC 9
CS 6	Fully contained process	PROC 1
CS 7	Batch process in closed system	PROC 3
CS 8	Open or semi-closed wet chemical process	PROC 4
CS 9	Laboratory analyses	PROC 15
CS 10	Wet cleaning	PROC 8a

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: <= 28 tonnes/year *65.8 tonnes dihydrogen tetrachloropalladate (28.0 tonnes Pd metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.1 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 9.18. 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:** 5.62E-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:** 3E-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 9.19. 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:** 1.52E-5 mg/L RCR = 0.338	Final RCR = 0.338
Sediment (freshwater)	Pd dissolved	**Local PEC:** 0.037 mg/kg dw RCR = 0.136	Final RCR = 0.136
Sewage Treatment Plant	Pd dissolved	**Local PEC:** 4.98E-4 mg/L RCR = 9.47E-4	Final RCR < 0.01

Protection target	Assessment entity	Exposure concentration	Risk quantification
Agricultural soil	Pd dissolved	**Local PEC:** 2.13E-3 mg/kg dw RCR = 0.108	Final RCR = 0.108

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: <= 28 tonnes/year *65.8 tonnes dihydrogen tetrachloropalladate (28.0 tonnes Pd metal equivalent); 90P from sector data*
• Daily use amount at site: <= 0.1 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 9.20. 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:** 5.62E-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:** 3E-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:**

Release	Assessment entity	Release estimation method	Explanations
			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 9.21. 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-6 mg/L RCR = 0.044	Final RCR = 0.044
Sediment (freshwater)	Pd dissolved	**Local PEC:** 4.9E-3 mg/kg dw RCR = 0.018	Final RCR = 0.018
Agricultural soil	Pd dissolved	**Local PEC:** 2.13E-3 mg/kg dw RCR = 0.108	Final RCR = 0.108

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 *1.18 tonnes dihydrogen tetrachloropalladate (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 9.22. 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

Release	Assessment entity	Release estimation method	Explanations
			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.

9.2.3.3. 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 9.23. 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: Handling/Transfer of solutions (PROC 8b)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.2.4.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1
Technical and organisational conditions and measures	

	Method
• Contact level: Intermittent	MEASE 1
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.2.4.2. Exposure and risks for workers

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

Table 9.24. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	3.43 µg/kg bw/day (MEASE 1) RCR = 1.11E-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 Dihydrogen tetrachloropalladate(2-):
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: Small scale handling/transfer of solutions (PROC 9)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.2.5.2. Exposure and risks for workers

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

Table 9.25. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Combined routes, systemic, long-term			Final RCR = 0.012

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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: Fully contained process (PROC 1)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Level of containment: Closed process	MEASE 1
• Pattern of use: Closed system without breaches	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1

	Method
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.2.6.2. Exposure and risks for workers

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

Table 9.26. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	1 µg/m³ (MEASE 1) RCR = 9.17E-5	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	1.71 µg/kg bw/day (MEASE 1) RCR = 5.52E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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: Batch process in closed system (PROC 3)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.2.7.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	

	Method
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Level of containment: Closed process	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.2.7.2. Exposure and risks for workers

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

Table 9.27. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	1.71 µg/kg bw/day (MEASE 1) RCR = 5.52E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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.

9.2.8. Worker CS 8: Open or semi-closed wet chemical process (PROC 4)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.2.8.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.2.8.2. Exposure and risks for workers

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

Table 9.28. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	50 µg/m³ (MEASE 1) RCR = 4.59E-3	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	3.43 µg/kg bw/day (MEASE 1) RCR = 1.11E-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 Dihydrogen tetrachloropalladate(2-):
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.

9.2.9. Worker CS 9: Laboratory analyses (PROC 15)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.2.9.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.2.9.2. Exposure and risks for workers

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

Table 9.29. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Inhalation, local, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1)	Qualitative risk
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	17.14 µg/kg bw/day (MEASE 1) RCR = 5.53E-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 Dihydrogen tetrachloropalladate(2-):
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.

9.2.10. Worker CS 10: Wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.2.10.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Immediate removal of splashes: Splashes should be removed immediately before drying of the substance	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
• 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
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.2.10.2. Exposure and risks for workers

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

Table 9.30. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	50 µg/m³ (MEASE 1) RCR = 4.59E-3	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Combined routes, systemic, long-term			Final RCR = 0.016

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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	Small scale handling/transfer of solutions	PROC 9
CS 3	Fully contained process	PROC 1
CS 4	Closed batch process	PROC 3
CS 5	Laboratory analyses	PROC 15
CS 6	Wet cleaning	PROC 8a

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 *15.3 tonnes dihydrogen tetrachloropalladate (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%

Assessment entities	Pd dissolved
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 9.31. 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 9.32. 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 (freshwater)	Pd dissolved	**Local PEC:** 0.049 mg/kg dw RCR = 0.179	Final RCR = 0.179

Protection target	Assessment entity	Exposure concentration	Risk quantification
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: Small scale handling/transfer of solutions (PROC 9)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.3.2.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.3.2.2. 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	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011
Combined routes, systemic, long-term			Final RCR = 0.012

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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.

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

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Level of containment: Closed process	MEASE 1
• Pattern of use: Closed system without breaches	MEASE 1

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.3.3.2. Exposure and risks for workers

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

Table 9.34. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	1 µg/m³ (MEASE 1) RCR = 9.17E-5	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	1.71 µg/kg bw/day (MEASE 1) RCR = 5.52E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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: Dihydrogen tetrachloropalladate for OCC assessment

9.3.4.1. Conditions of use

	Method
Product (article) characteristics	

	Method
• 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Level of containment: Closed process	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.3.4.2. Exposure and risks for workers

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

Table 9.35. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	1.71 µg/kg bw/day (MEASE 1) RCR = 5.52E-4	Final RCR < 0.01
Combined routes, systemic, long-term			Final RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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: Laboratory analyses (PROC 15)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.3.5.2. Exposure and risks for workers

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

Table 9.36. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	17.14 µg/kg bw/day (MEASE 1) RCR = 5.53E-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 Dihydrogen tetrachloropalladate(2-):
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: Wet cleaning (PROC 8a)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Immediate removal of splashes: Splashes should be removed immediately before	MEASE 1

	Method
drying of the substance	
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
• 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
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.3.6.2. Exposure and risks for workers

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

Table 9.37. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	50 µg/m³ (MEASE 1) RCR = 4.59E-3	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011
Combined routes, systemic, long-term			Final RCR = 0.016

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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.

9.4. Exposure scenario 4: Formulation or re-packing - Formulation

Market sector: Treatment of surfaces
Product category formulated: PC 14: Metal surface treatment products

Environment contributing scenario(s):		
CS 1	Formulation	ERC 2
Worker contributing scenario(s):		
CS 2	Handling/Transfer of solutions	PROC 8b
CS 3	Small scale handling/transfer of solutions	PROC 9
CS 4	Formulation step	PROC 4
CS 5	Wet cleaning	PROC 8a

9.4.1. Env CS 1: Formulation (ERC 2)

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

9.4.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 2.2 tonnes/year *5.17 tonnes dihydrogen tetrachloropalladate (2.20 tonnes Pd metal equivalent)*
• Daily use amount at site: <= 7.86E-3 tonnes/day *Based on 280 days per year per site (standard for sector; see ES1)*
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.

9.4.1.2. 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 9.38. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 0.02% **Release factor after on site RMM:** 0.02% **Local release rate:** 1.57E-3 kg/day **Explanation:** On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency >99 % (sector data) Release factor after on-site treatment: 200 g/T (99% treatment WWTP efficiency applied to 2% RF before on-site treatment)
Air	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 1E-3% **Release factor after on site RMM:** 1E-3% **Local release rate:** 7.86E-5 kg/day **Explanation:** Treatment of air emissions by filters, electrostatic precipitation and/or wet scrubbers. (SpERC for 'Formulation of metal compounds') Release factor after on-site treatment: 10 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.

9.4.1.3. 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 9.39. 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:** 2.03E-5 mg/L RCR = 0.452	Final RCR = 0.452
Sediment (freshwater)	Pd dissolved	**Local PEC:** 0.05 mg/kg dw RCR = 0.182	Final RCR = 0.182
Sewage Treatment Plant	Pd dissolved	**Local PEC:** 2.09E-4 mg/L RCR = 3.97E-4	Final RCR < 0.01
Agricultural soil	Pd dissolved	**Local PEC:** 1.86E-3 mg/kg dw RCR = 0.094	Final RCR = 0.094

9.4.2. Worker CS 2: Handling/Transfer of solutions (PROC 8b)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.4.2.1. Conditions of use

	Method
Product (article) characteristics	

	Method
• 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.4.2.2. Exposure and risks for workers

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

Table 9.40. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	3.43 µg/kg bw/day (MEASE 1) RCR = 1.11E-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 Dihydrogen tetrachloropalladate(2-):

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.

9.4.3. Worker CS 3: Small scale handling/transfer of solutions (PROC 9)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.4.3.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.4.3.2. Exposure and risks for workers

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

Table 9.41. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011
Combined routes, systemic, long-term			Final RCR = 0.012

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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.

9.4.4. Worker CS 4: Formulation step (PROC 4)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.4.4.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1

	Method
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.4.4.2. Exposure and risks for workers

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

Table 9.42. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	50 µg/m³ (MEASE 1) RCR = 4.59E-3	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	3.43 µg/kg bw/day (MEASE 1) RCR = 1.11E-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 Dihydrogen tetrachloropalladate(2-):
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.

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

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.4.5.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Immediate removal of splashes: Splashes should be removed immediately before drying of the substance	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
• 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
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.4.5.2. Exposure and risks for workers

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

Table 9.43. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	50 µg/m³ (MEASE 1) RCR = 4.59E-3	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Combined routes, systemic, long-term			Final RCR = 0.016

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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.

9.5. Exposure scenario 5: Use at industrial sites - Use in metal surface treatment

Market sector: Treatment of surfaces
Product category used: PC 14: Metal surface treatment products
Sector of use: SU 15: Manufacture of fabricated metal products, except machinery and equipment

Environment contributing scenario(s):		
CS 1	Use in metal surface treatment	ERC 5
Worker contributing scenario(s):		
CS 2	Handling/Transfer of solutions	PROC 8b
CS 3	Small scale handling/transfer of solutions	PROC 9
CS 4	Open or semi-closed wet chemical process	PROC 4
CS 5	Plating	PROC 13
CS 6	Wet cleaning	PROC 8a

Subsequent service life exposure scenario(s):
ES6: Service life (consumers) - Service life of treated articles

Explanation on the approach taken for the ES:

During this use, the substance is chemically transformed into palladium metal. Any subsequent handling steps after transformation of the substance are not in the scope of this ES.

9.5.1. Env CS 1: Use in metal surface treatment (ERC 5)

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

9.5.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Annual use amount at site: <= 0.72 tonnes/year *1.69 tonnes dihydrogen tetrachloropalladate (0.72 tonnes Pd equivalent)*
• Daily use amount at site: <= 3.27E-3 tonnes/day *Based on 220 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%

Assessment entities	Pd dissolved
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.

9.5.1.2. 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 9.44. Local releases to the environment

Release	Assessment entity	Release estimation method	Explanations
Water	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 0.05% **Release factor after on site RMM:** 0.05% **Local release rate:** 1.64E-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 'Industrial use of metals and metal compounds in metallic coating') Release factor after on-site treatment: 500 g/T (10% of SpERC RF for wastewater)
Air	Pd dissolved	Estimated release factor	**Release factor before on site RMM:** 0.02% **Release factor after on site RMM:** 0.02% **Local release rate:** 6.54E-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 'Industrial use of metals and metal compounds in metallic coating') Release factor after on-site treatment: 200 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.

9.5.1.3. 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 9.45. 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:** 2.11E-5 mg/L RCR = 0.47	Final RCR = 0.47
Sediment (freshwater)	Pd dissolved	**Local PEC:** 0.052 mg/kg dw RCR = 0.19	Final RCR = 0.19

Protection target	Assessment entity	Exposure concentration	Risk quantification
Sewage Treatment Plant	Pd dissolved	**Local PEC:** 2.17E-4 mg/L RCR = 4.13E-4	Final RCR < 0.01
Agricultural soil	Pd dissolved	**Local PEC:** 1.9E-3 mg/kg dw RCR = 0.096	Final RCR = 0.096

9.5.2. Worker CS 2: Handling/Transfer of solutions (PROC 8b)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.5.2.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.5.2.2. Exposure and risks for workers

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

Table 9.46. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011
Combined routes, systemic, long-term			Final RCR = 0.012

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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.

9.5.3. Worker CS 3: Small scale handling/transfer of solutions (PROC 9)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.5.3.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.5.3.2. Exposure and risks for workers

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

Table 9.47. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011
Combined routes, systemic, long-term			Final RCR = 0.012

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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.

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

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.5.4.1. Conditions of use

	Method
Product (article) characteristics	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1

	Method
• Maximum emission potential of the substance: Very low	MEASE 1
• Physical form of the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Non-direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.5.4.2. Exposure and risks for workers

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

Table 9.48. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	50 µg/m³ (MEASE 1) RCR = 4.59E-3	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	3.43 µg/kg bw/day (MEASE 1) RCR = 1.11E-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 Dihydrogen tetrachloropalladate(2-):
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.

9.5.5. Worker CS 5: Plating (PROC 13)

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.5.5.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.5.5.2. Exposure and risks for workers

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

Table 9.49. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	10 µg/m³ (MEASE 1) RCR = 9.17E-4	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011
Combined routes, systemic, long-term			Final RCR = 0.012

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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.

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

Assessment entity group used for the assessment of this contributing scenario: Dihydrogen tetrachloropalladate for OCC assessment

9.5.6.1. 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 the used product	MEASE 1
• Physical form of substance: Solution	MEASE 1
• Percentage (w/w) of substance in mixture/article: <= 100 %	MEASE 1
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8 h/day	MEASE 1
• 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
• Local exhaust ventilation: No	MEASE 1
• Immediate removal of splashes: Splashes should be removed immediately before drying of the substance	MEASE 1
• Room ventilation: Basic (up to 3 ACH)	MEASE 1
• Pattern of exposure control: Direct handling	MEASE 1

	Method
• Occupational Health and Safety Management System: Advanced	MEASE 1
• Pattern of use: Non-dispersive use	MEASE 1
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No	MEASE 1
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation	
• Face/eye protection: No	
• Respiratory protection: No	MEASE 1
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes	
• 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
Other conditions affecting workers exposure	
• Place of use: Indoor	MEASE 1
• Operating temperature: <= 40 °C	MEASE 1

9.5.6.2. Exposure and risks for workers

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

Table 9.50. Exposure concentrations and risks for workers

Route of exposure and type of effects	Assessment entity	Exposure concentration	Risk quantification
Inhalation, systemic, long term	Dihydrogen tetrachloropalladate(2-)	50 µg/m³ (MEASE 1) RCR = 4.59E-3	Final RCR < 0.01
Dermal, systemic, long term	Dihydrogen tetrachloropalladate(2-)	34.29 µg/kg bw/day (MEASE 1) RCR = 0.011	Final RCR = 0.011
Combined routes, systemic, long-term			Final RCR = 0.016

Remarks on exposure data from external estimation tools:

MEASE 1 for Dihydrogen tetrachloropalladate(2-):
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.

9.6. Exposure scenario 6: Service life (consumers) - Service life of treated articles

Market sector: Treatment of surfaces

Environment contributing scenario(s):		
CS 1	Service life of treated articles	**ERC 10a**, ERC 11a
Consumer contributing scenario(s):		
CS 2	Service life of treated articles	AC 7

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):
ES5: Use at industrial sites - Use in metal surface treatment

Further description of the use:

After metal surface treatment the treated articles are not expected to contain dihydrogen tetrachloropalladate since the substance is transformed to palladium metal during deposition on the article.

Explanation on the approach taken for the ES:

The treated articles contain palladium in metallic form with > 99.9% purity, as a result the articles don’t contain residual dihydrogen tetrachloropalladate in concentrations above those triggering classification.
Palladium metal (EC 231-115-6) is registered in the > 10 T/y tonnage band and does not meet the criteria to be classified as a hazardous substance hence no further exposure assessment is required.

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 anypalladium 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 all exposure levels were derived for a full-shift exposure time and a safe use was demonstrated for each contributing scenario. Thus, by demonstrating safe use for individual contributing scenarios it is assured that a combination of activities within a single shift, could not exceed the highest calculated RCR for 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	24.62 kg/year
Air	Pd dissolved	8.26 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

Remarks on risk characterisation for regional concentrations:

To derive the regional background concentration for environmental compartments two approaches have been followed; EUSES modelling based on regional production volume for the aquatic environment, and data from peer-reviewed, published literature for the terrestrial compartment.
For the derivation of the regional background concentrations in the aquatic environment, the total tonnage of all palladium (Pd) compounds produced in the EU was sub-divided by region. The value input to modelling was the maximum proportion of Pd compounds produced in a single region. This regional assumption was combined with emission characteristics from the Pd manufacturing and processing sector data, STP removal efficiency and phys-chem properties to perform calculations of the regional PEC concentrations for freshwater and freshwater sediment and marine water and sediment. The estimated regional background PECs were then incorporated into all GESs.
For the derivation of regional background concentrations in the terrestrial environment, data from the geochemical mapping of agricultural and grazing land soil of Europe (GEMAS) project were utilised. GEMAS is a project conducted by the EuroGeoSurveys Geochemistry Expert Group and Eurometaux for the production of exposure data on metals in agricultural and grazing land soil and soil properties, at the European scale.

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

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

Details on test material: - Name of test material (as cited in study report): dihydrogen tetrachloropalladate(II)-solution - Substance type: brown liquid - Physical state: liquid - Analytical purity: 99.95% - Impurities (identity and concentrations): no data - Composition of test material, percentage of components: 47% of H2(PdCl4) in the solution - Purity test date: no data - Lot/batch No.: 4515932529 - Expiration date of the lot/batch: 12 September 2003 - Stability under test conditions: no data - Storage condition of test material: room temperature in the dark

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

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

Details on test material: - Name of test material (as cited in study report): Dihydrogen tetrachloropalladate(II), solution - Physical state: brown liquid - Analytical purity: Not specified. - Impurities (identity (concentration in ppm)): Pt (94), Ru (<2), Rh (73), Ir (<2), Au (<2), Ag (10), Al (<2), Ca (3), Co (<2), Cr (<1), Cu (<2), Fe (8), Mg (<1), Mn (<1), Ni (<1), Pb (<3), Sb (<5), Si (<10), Sn (41), Zn (<1) - Composition of test material, percentage of components: 47% w/v dihydrogen tetrachloropalladate(II); 16% w/v hydrogen chloride. Palladium content 20.00% w/v - Isomers composition: Not specified. - Purity test date: Not specified. - Lot/batch No.: 21113 - Expiration date of the lot/batch: 31 December 2016 - Stability under test conditions: Not specified. - Storage condition of test material: Room temperature.

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

Composition type: Constituent	**Reference substance:** Dihydrogen tetrachloropalladate (II) solution EC no.: CAS no: IUPAC name: Dihydrogen tetrachloropalladate (II) solution	**Concentration range:**
Composition type: Constituent	**Reference substance:** dihydrogen tetrachloropalladate(2-) EC no.: CAS no: 16970-55-1 IUPAC name: palladium(4+) tetrachloride	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Palladium chloride solution (hydrogen tetrachloropalladate soln.) - Physical state: Reddish-brown liquid - Analytical purity: Not specified. - Impurities (identity and concentrations): Not specified. - Composition of test material, percentage of components: palladium content 23.13% w/w. Cl:Pd molar ratio 3.8. - Isomers composition: Not specified. - Purity test date: Not specified. - Lot/batch No.: DY0169 - Expiration date of the lot/batch: 11 June 2017 - Stability under test conditions: Not specified. -Other: palladium (II) chloride spontaneously equilibrates between a mixture of hydrogen tetrachloropalladate (II) and palladium (II) chloride in aqueous solution.

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

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

Details on test material: - Name of test material (as cited in study report): dihydrogen tetrachloropalladate(II) - Substance type: brown liquid - Physical state: liquid - Analytical purity: 99.95% - Impurities (identity and concentrations): 0.05% - Composition of test material, percentage of components: 47% by weight of dihydrogen tetrachloropalladate(II) in solution - Purity test date: no data - Lot/batch No.: 4515932529 - Expiration date of the lot/batch: 12 September 2003 - Stability under test conditions: at least 96 hr (in water) - Storage condition of test material: room temperature, in dark - Other:

Test material: **disodium tetrachloropalladate / 13820-53-6 / 237-502-6**
Form: **not specified**

Composition type: Constituent	**Reference substance:** disodium tetrachloropalladate EC no.: CAS no: 13820-53-6 IUPAC name: disodium tetrachloropalladate	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Sodium tetrachloropalladate (Na2PdCl4) - 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: 2, 3 or 4% Na2PdCl4 in petrolatum - 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 - Other: Na2PdCl4 was ground with a porcelainmortar and pestle. Then 2, 3 and 4 g were added to 98, 97 and 96 g of pet., respectively. Na2PdCl4 with the pet. was then suspended in a glass laboratory bottle by heating (55 deg C) in a ultrasonic cleaning unit with intermittent stirring for 4 hr until a homogeneous suspension was obtained. Sterile syringes were then filled with 2%, 3% and 4% Na2PdCl4 pet. and labelled. One batch for each test concentration was used to prepare the syringes for all test centres.

Test material: **disodium tetrachloropalladate / 13820-53-6 / 237-502-6**

Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** Disodium tetrachloropalladate EC no.: CAS no: 13820-53-6 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): sodium chloropalladite - Substance type: brown powder - Physical state: solid - Analytical purity: no data - Impurities (identity and concentrations): no data - Composition of test material, percentage of components: no data - Purity test date: no data - Lot/batch No.: 041118/A - Expiration date of the lot/batch: no data - Stability under test conditions: no data - Storage condition of test material: supplied in closed glass jar; no further details

Test material: **Dihydrogen tetrachloropalladate**
Form:

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

Test material: **dipotassium tetrachloropalladate / 10025-98-6 / 233-049-3**
Form: **not specified**

Composition type: Constituent	**Reference substance:** Dipotassium tetrachloropalladate EC no.: CAS no: 10025-98-6 IUPAC name:	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): K2PdCl4 - Molecular formula (if other than submission substance): K2PdCl4 - Molecular weight (if other than submission substance): 326.4 g/mol - Smiles notation (if other than submission substance): [Pd-2](Cl)(Cl)(Cl)Cl.[K+].[K+] - InChl (if other than submission substance): 1S/4ClH.2K.Pd/h4*1H;;;/q;;;;2*+1;+2/p-4 - Structural formula attached as image file (if other than submission substance): see Fig. - 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 - Lot/batch No.: no data - Expiration date of the lot/batch: no data - Stability under test conditions: no data

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

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

Details on test material: - Name of test material (as cited in study report): dihydrogen tetrachloropalladate (II)-solution - Substance type: brown liquid - Physical state: liquid - Analytical purity: 99.95% - Impurities (identity and concentrations): no data - Composition of test material, percentage of components: 47% (w/v) of dihydrogen tetrachloropalladate(II) in the solution - Isomers composition: - Purity test date: no data - Lot/batch No.: 4515932529 - Expiration date of the lot/batch: 12 September 2003 - Stability under test conditions: reported as stable in water for at least 96 hr - Storage condition of test material: at room temperature in dark; stable

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

Composition type: Constituent	**Reference substance:** Dihydrogen tetrachloropalladate EC no.:	**Concentration range:**

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

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

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: **Dihydrogen tetrachloropalladate(II) solution**
Form: **aqueous solution**

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

Constituent	Palladium Hydrogen Carbonate EC no.: CAS no: IUPAC name: Tetrammine Palladium Hydrogen Carbonate	

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: **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: **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.: 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:	**Reference substance:**	**Concentration range:**
Constituent	Diamminedichloropalladium EC no.: 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: **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.: 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.: 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.: CAS no: 7647-10-1 IUPAC name: palladium(2+)	**Concentration range:**

	dichloride	

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.: CAS no: 14323-43-4 IUPAC name: Diamminedichloropalladium	

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

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:

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: