CHEMICAL SAFETY REPORT

Substance Name: Diammonium sodium hexakis(nitro-N)rhodate

EC Number: 264-713-0

CAS Number: 64164-17-6

Registrant's Identity:

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Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

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

The above part A element applies to: 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: 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: all uses

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

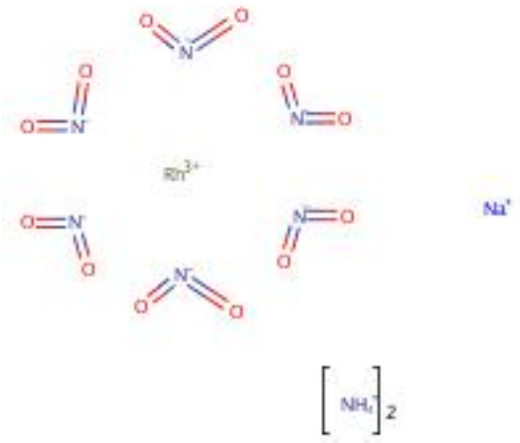
The substance Diammonium sodium hexakis(nitro-N)rhodate is a mono-constituent substance (inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).
The following public name is used:

Table 1.1. Substance identity

EC number:	264-713-0
EC name:	diammonium sodium hexakis(nitrito-N)rhodate
CAS number (EC inventory):	64164-17-6
CAS number:	64164-17-6
IUPAC name:	Diammonium sodium hexakis(nitro-N)rhodate
Molecular formula:	H4N.1/2N6O12Rh.1/2Na
Molecular weight range:	438.007

Structural formula:

Figure 1.1. 64164-17-6.png



1.2. Composition of the substance

Overall information on composition

Composition	Related composition(s)
Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘high purity’ (boundary composition of the substance)	
Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘low impurity’ (boundary composition of the substance)	
Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘high impurity’ (boundary composition of the substance)	

Name: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘high purity’

State/form: solid: particulate/powder

Degree of purity: >=80 - <=100 % (w/w)

Description: Mono-constituent substance. Some or all of the listed impurities may be present in the substance. However, the combined concentration of impurities classified as Aquatic acute 1 or Aquatic chronic 1 is below the classification cut-off for the substance to be assigned either of these environmental classifications.

Table 1.2. Constituents (Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘high purity’)

Constituent	Typical concentration	Concentration range	Remarks
Diammonium sodium hexakis(nitro-N)rhodate EC no.: 264-713-0	93 % (w/w)	>=80 - <=100 % (w/w)	

Table 1.3. Impurities (Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘high purity’)

Constituent	Typical concentration	Concentration range	Remarks
ammonium chloride EC	7 % (w/w)	>=3 - <=11 % (w/w)	

no.: 235-186-4			
Precious metal impurities EC no.:	<1 % (w/w)	>=0 - <=1 % (w/w)	Precious metal impurities e.g. Ag, Au, Ir, Pd, Pt, Ru.
copper dichloride EC no.: 231-210-2	<1 % (w/w)	>=0 - <=1 % (w/w)	
Nickel chloride EC no.: 253-399-0	<0.01 % (w/w)	>=0 - <0.01 % (w/w)	
chromium trichloride EC no.: 233-038-3	<1 % (w/w)	>=0 - <=1 % (w/w)	
Lead chloride EC no.: 231-845-5	<0.3 % (w/w)	>=0 - <0.3 % (w/w)	
Several minor (especially metallic) impurities EC no.:	<1 % (w/w)	>=0 - <=1 % (w/w)	Several minor (especially metallic) 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 e.g. Bi, Fe, Mg, Te.

Name: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘low impurity’

State/form: solid: particulate/powder

Degree of purity: >=80 - <=100 % (w/w)

Description: Mono-constituent substance. Some or all of the listed impurities may be present in the substance. However, the combined concentration of impurities classified as Aquatic acute 1 or Aquatic chronic 1 is below the classification cut-off for the substance to be assigned either of these environmental classifications.

Table 1.4. Constituents (Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘low impurity’)

Constituent	Typical concentration	Concentration range	Remarks
Diammonium sodium hexakis(nitro-N)rhodate	93 % (w/w)	>=80 - <=100 % (w/w)	

EC no.: 264-713-0			

Table 1.5. Impurities (Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition 'low impurity')

Constituent	Typical concentration	Concentration range	Remarks
ammonium chloride EC no.: 235-186-4	7 % (w/w)	>=3 - <=11 % (w/w)	
Precious metal impurities EC no.:	<1 % (w/w)	>=0 - <=1 % (w/w)	Precious metal impurities e.g. Ag, Au, Ir, Pd, Pt, Ru.
copper dichloride EC no.: 231-210-2	<1 % (w/w)	>=0 - <=1 % (w/w)	
Nickel chloride EC no.: 253-399-0	<0.1 % (w/w)	>=0.01 - <0.1 % (w/w)	
chromium trichloride EC no.: 233-038-3	<1 % (w/w)	>=0 - <=1 % (w/w)	
Lead chloride EC no.: 231-845-5	<0.3 % (w/w)	>=0 - <0.3 % (w/w)	
Several minor (especially metallic) impurities EC no.:	<1 % (w/w)	>=0 - <=1 % (w/w)	Several minor (especially metallic) 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 e.g. Bi, Fe, Mg, Te.

Name: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition 'high impurity'

State/form: solid: particulate/powder

Degree of purity: >=80 - <=100 % (w/w)

Description: Mono-constituent substance. Some or all of the listed impurities may be present in the substance. However, the combined concentration of impurities classified as Aquatic acute 1 or Aquatic chronic 1 is below the classification cut-off for the substance to be assigned either of these environmental classifications.

Table 1.6. Constituents (Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition 'high impurity')

Constituent	Typical concentration	Concentration range	Remarks
Diammonium sodium hexakis(nitro-N)rhodate EC no.: 264-713-0	93 % (w/w)	>=80 - <=100 % (w/w)	

Table 1.7. Impurities (Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition 'high impurity')

Constituent	Typical concentration	Concentration range	Remarks
ammonium chloride EC no.: 235-186-4	7 % (w/w)	>=3 - <=11 % (w/w)	
Precious metal impurities EC no.:	<1 % (w/w)	>=0 - <=1 % (w/w)	Precious metal impurities e.g. Ag, Au, Ir, Pd, Pt, Ru.
copper dichloride EC no.: 231-210-2	<1 % (w/w)	>=0 - <=1 % (w/w)	
Nickel chloride EC no.: 253-399-0	<0.5 % (w/w)	>=0.1 - <0.5 % (w/w)	
chromium trichloride EC no.: 233-038-3	<1 % (w/w)	>=0 - <=1 % (w/w)	
Lead chloride EC no.: 231-845-5	<0.5 % (w/w)	>=0.3 - <0.5 % (w/w)	
Several minor (especially metallic) impurities EC no.:	<1 % (w/w)	>=0 - <=1 % (w/w)	Several minor (especially metallic) 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 e.g. Bi, Fe, Mg, Te.

1.3. Physicochemical properties

Table 1.8 Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state	Diammonium sodium hexakis(nitrito-N)rhodate is a green solid.	**Value used for CSA:** solid at 20°C and 101.3 kPa Data on the appearance and physical state of the substance is taken from the test material section of a GLP-compliant study on the physico-chemical properties of the material (Atwal and Tremain 2011). Diammonium sodium hexakis(nitrito-N)rhodate is a green solid.
Melting / freezing point	Diammonium sodium hexakis(nitrito-N)rhodate was determined to decompose from approximately 140°C (414 K) with no definitive signs of melting below 450°C (724 K).	**Value used for CSA:** Atwal and Tremain (2011) is a GLP compliant study following OECD guideline 102 and is considered suitable for use as the key study for this endpoint. Diammonium sodium hexakis(nitrito-N)rhodate was determined to decompose from approximately 140°C (414 K) with no definitive signs of melting below 450°C (724 K).
Relative density	The density of diammonium sodium hexakis(nitrito-N)rhodate was determined to be 2.42 g/cm^3 at 25°C.	**Value used for CSA:** 2.42 g/cm^3 at 20°C Potthoff (2011) is a non-GLP study but follows a standard test method and is considered suitable for use as the key study for this endpoint. The density of diammonium sodium hexakis(nitrito-N)rhodate was determined to be 2.42 g/cm^3 at 25°C.
Granulometry	Two samples of diammonium sodium hexakis(nitrito-N)rhodate were tested,	Atwal and Tremain (2011) is a GLP compliant study following OECD 110

	the first in a screening test and the second for particle size analysis and specific surface area. In the screening test, the proportion of diammonium sodium hexakis (nitrito-N)rhodate < 100 µm was 0.696 %. The particle size analysis determined the average 10th, 50th and 90th percentile particle sizes for diammonium sodium hexakis(nitrito-N)rhodate were 1.51, 9.3 and 43 µm, respectively. The specific surface area was determined as 1.09 ± 0.01 m^2/g.	(screening method) and is considered suitable for use as the key study for this endpoint. For the sample tested, the proportion of diammonium sodium hexakis (nitrito-N)rhodate < 100 µm was 0.696 %. Pothoff (2012) is a non-GLP experimental study that follows standard test guidelines and is also suitable for use as a key study for assessing this endpoint. The sample was analysed for particle size distribution after dry dispersion and N-BET. The average 10th, 50th and 90th percentile particle sizes for diammonium sodium hexakis(nitrito-N)rhodate were 1.51, 9.3 and 43 µm, respectively. The specific surface area was determined as 1.09 ± 0.01 m^2/g. The dustiness of diammonium sodium hexakis(nitrito-N)rhodate was tested in a modified Heubach procedure according to the guideline DIN 55992-1:2006. The study is non-GLP, but follows a standard guideline and is considered to be reliable. The total dustiness of diammonium sodium hexakis(nitrito-N)rhodate was determined to be 237.16 mg/g. The inhalable fraction was 147.63 mg/g, the thoracic fraction was 44.65 mg/g and the respirable fraction was 7.98 mg/g. The Mass Median Aerodynamic Diameter (MMAD) was 28.96 µm with Geometric Standard Deviation of 2.3 µm.

Water solubility	The water solubility of diammonium sodium hexakis(nitrito-N)rhodate has been determined to be 0.76 g/L of solution at 20.0 - 21.5 °C.	**Value used for CSA:** 0.76g/L at 20°C Gregory (2014) is a published paper and followed a standard water solubility test method. It is considered suitable for use as the key study for this endpoint. The water solubility of diammonium sodium hexakis(nitrito-N)rhodate was reported as 0.76 g/L at 20°C
Autoflammability / self-ignition temperature	Diammonium sodium hexakis(nitrito-N)rhodate is classified in Category 1 for self-heating substances and mixtures, in accordance with Regulation (EC) 1272./2008 of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, as the temperature of the test item exceeded the oven temperature by approximately 70°C during the period the oven temperature was held at 140°C.	**Value used for CSA:** Atwal and Tremain (2011) is a GLP compliant study following a modified UN N4 method and is considered suitable for use as the key study for this endpoint. The temperature of diammonium sodium hexakis(nitrito-N)rhodate exceeded the oven temperature by approximately 70°C during the period the oven temperature was held at 140°C. The result is considered positive, therefore, diammonium sodium hexakis(nitrito-N)rhodate is classified in Category 1 for self-heating substances and mixtures, in accordance with Regulation (EC) 1272./2008 of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures.
Flammability	Diammonium sodium hexakis(nitrito-N)rhodate is not classified as a flammable solid under Division 4.1 as it failed to ignite in the preliminary screening test.	**Value used for CSA:** not classified Atwal and Tremain (2011) is a GLP compliant study following UN method N1 and is considered suitable for use as the key study for this endpoint.

		Diammonium sodium hexakis(nitrito-N)rhodate is not classified as a flammable solid under Division 4.1 as it failed to ignite in the preliminary screening test.
Explosive properties	No explosions were observed up to the maximum impact energy applied of 50 J, and the result is considered negative for the BAM fall hammer test for shock; no explosions were observed using the maximum friction load of 360 N and the result is considered negative for the BAM friction test; an explosion was observed with a limiting orifice diameter of 2mm and the result is considered positive (diammonium sodium hexakis(nitrito-N)rhodate showed a violent effect on heating under confinement) for the Koenen test for thermal sensitivity.	**Value used for CSA:** Atwal and Tremain (2011) is a GLP compliant study following standard test guidelines which is considered suitable for use as a key study for this endpoint. No explosions were observed up to the maximum impact energy applied of 50 J, and the result is considered negative for the BAM fall hammer test for shock; no explosions were observed using the maximum friction load of 360 N and the result is considered negative for the BAM friction test; an explosion was observed with a limiting orifice diameter of 2mm and the result is considered positive (diammonium sodium hexakis(nitrito-N)rhodate showed a violent effect on heating under confinement) for the Koenen test for thermal sensitivity.
Oxidising properties	Diammonium sodium hexakis(nitrito-N)rhodate is classified in Category 3 for oxidising solids in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on classification, Labelling and Packaging of Substances and Mixtures.	**Value used for CSA:** oxidising This is a GLP compliant study following UN method O1 (oxidising solids) which is considered suitable for use for this endpoint. Diammonium sodium hexakis(nitrito-N)rhodate is classified in Category 3 for oxidising solids in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on classification,

		Labelling and Packaging of Substances and Mixtures.

Data waiving

Information requirement: Boiling point

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is a solid which decomposes before boiling [study scientifically not necessary / other information available]

Information requirement: Vapour pressure

Reason: study scientifically not necessary / other information available

Justification: see 'Remark' - Diammonium sodium hexakis(nitrito-N)rhodate is an inorganic substance that forms a crystal lattice. Upon heating, it decomposes from approximately at 260°C. It is scientifically not plausible that the substance could exist in molecular form in the gas phase due to its solid state structure. Thus, the concept of vapour pressure, i.e. the saturation pressure above a solid or liquid does not apply.

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

Reason: study scientifically not necessary / other information available

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

Information requirement: Surface tension

Reason: study scientifically not necessary / other information available

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

the study does not need to be conducted because surface activity is not a desired property of the material [study scientifically not necessary / other information available]

Information requirement: Flash point

Reason: study scientifically not necessary / other information available

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

the study does not need to be conducted because the flash point is only relevant to liquids and low melting point solids [study technically not feasible] - In accordance with ECHA (2015) Guidance on

information requirements and chemical safety assessment, chapter R7a: endpoint specific guidance, the flash point study does not need to be conducted as this substance is a solid at room temperature.;

the study does not need to be conducted because decomposition occurred during the melting point study [study technically not feasible]

Discussion of physicochemical properties

Additional information:

Physico-chemical endpoints are completed for this substance based on reliable test data or appropriate data waivers.

Based on a reliable study following a modified UN N4 method, this substance is classified as a Category 1 self-heating substance (H251) and based on the results from a study following UN method O1 it is classified as a Category 3 oxidising solid (H272).

2. MANUFACTURE AND USES

2.1. Manufacture

Table 2.1. Manufacture

	Manufacture
M-1	**Manufacture (of the substance as such)** Manufactured composition (see section 1.x): Further description of manufacturing process: A weakly acidic and impure aqueous solution of rhodium chloride is treated with sodium nitrite solution at ambient temperature. A solution of ammonium chloride is added to the stirred rhodium solution to precipitate the diammonium sodium hexakis(nitrito-N)rhodate salt. The intermediate diammonium sodium hexakis(nitrito-N)rhodate salt is filtered and washed with dilute ammonium chloride solution and then transferred to bins to await further processing. Contributing activity/technique for the environment : **- (ERC1)** Contributing activity/technique for the workers : **- (PROC 4)** **- (PROC 8b)** **- (PROC 26)**

2.2. Identified uses

Table 2.2. Uses at industrial sites

	Uses at industrial sites
IW-1	**Use as an intermediate** Related composition (see section 1.x): Further description of the use: Contributing activity/technique for the environment : **- (ERC6a)** Contributing activity/technique for the workers : **- (PROC 4)** **- (PROC 8b)** **- (PROC 26)** **Product Category used:** **Sector of end use:** SU 0: Other: NACE CODE C2441 Precious metal production

	Technical function of the substance: intermediate (precursor) Subsequent service life relevant for that use: no

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Substance: Diammonium hexakis(nitrito-N)rhodate - 'high purity'

Implementation: EU

Related composition: Boundary Composition - 'high purity'

The substance is classified as follows:

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

Hazard class	Hazard category	Hazard statement	Reason for no classification
Explosives:			conclusive but not sufficient for classification
Desensitised explosives:			data lacking
Flammable gases and chemically unstable gases:			conclusive but not sufficient for classification
Flammable aerosols:			conclusive but not sufficient for classification
Oxidising gases:			conclusive but not sufficient for classification
Gases under pressure:			conclusive but not sufficient for classification
Flammable liquids:			conclusive but not sufficient for classification
Flammable solids:			conclusive but not sufficient for classification
Self-reactive substances and			conclusive but not sufficient for

mixtures:			classification
Pyrophoric liquids:			conclusive but not sufficient for classification
Pyrophoric solids:			conclusive but not sufficient for classification
Self-heating substances and mixtures:	Self Heat. 1	H251: Self-heating: may catch fire.	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification
Oxidising liquids:			conclusive but not sufficient for classification
Oxidising solids:	Oxid. Solid 3	H272: May intensify fire; oxidiser.	
Organic peroxides:			conclusive but not sufficient for classification
Corrosive to metals:			conclusive but not sufficient for classification

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

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:			conclusive but not sufficient for classification
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking

Skin corrosion / irritation:			conclusive but not sufficient for classification
Serious damage / eye irritation:			conclusive but not sufficient for classification
Respiratory sensitisation:			data lacking
Skin sensitisation:			conclusive but not sufficient for classification
Aspiration hazard:			data lacking
Reproductive Toxicity:			conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:	Muta. 2	H341: Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.	
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:	Affected organs: Route of exposure:		data lacking
Specific target organ toxicity – repeated exposure:	Affected organs: Route of exposure:		conclusive but not sufficient for classification

Table 3.3. Classification and labelling according to CLP / GHS for the environment

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic			conclusive but not

environment (acute/short-term):			sufficient for classification
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 2	H411: Toxic to aquatic life with long lasting effects.	
M-Factor acute:			
M-Factor chronic:			
Hazardous to the ozone layer:			conclusive but not sufficient for classification

Signal word: Danger

Hazard pictogram:

Figure 3.1.



GHS09: environment

Figure 3.2.



GHS02: flame

Figure 3.3.



GHS03: flame over circle

Figure 3.4.



GHS08: health hazard

Hazard statements:

H251: Self-heating: may catch fire.

H272: May intensify fire; oxidiser.

H341: Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H411: 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 label before use.

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P220: Keep away from clothing or other combustible materials.

P221: Take any precaution to avoid mixing with combustibles...

P235+P410: Keep cool. Protect from sunlight.

P273: Avoid release to the environment.

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

P308+P313: IF exposed or concerned: Get medical advice/attention.

P370+P378: In case of fire: Use... to extinguish.

P391: Collect spillage.

P405: Store locked up.

P407: Maintain air gap between stacks or pallets.

P413: Store bulk masses greater than ... kg/... lbs at temperatures not exceeding ...°C/...°F.

P420: Store separately.

P501: Dispose of contents/container to ... …in accordance with local/regional/national /international regulations (to be specified). Manufacturer/supplier or the competent authority to

specify whether disposal requirements apply to contents, container or both.

Substance: Diammonium hexakis(nitrito-N)rhodate - 'low impurity'

Implementation: EU

Related composition: Boundary Composition - 'low impurity'

The substance is classified as follows:

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

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

			sufficient for classification
Pyrophoric solids:			conclusive but not sufficient for classification
Self-heating substances and mixtures:	Self Heat. 1	H251: Self-heating: may catch fire.	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification
Oxidising liquids:			conclusive but not sufficient for classification
Oxidising solids:	Oxid. Solid 3	H272: May intensify fire; oxidiser.	
Organic peroxides:			conclusive but not sufficient for classification
Corrosive to metals:			conclusive but not sufficient for classification

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

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:			conclusive but not sufficient for classification
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:			conclusive but not sufficient for

			classification
Serious damage / eye irritation:			conclusive but not sufficient for classification
Respiratory sensitisation:			data lacking
Skin sensitisation:	Skin Sens. 1	H317: May cause an allergic skin reaction.	
Aspiration hazard:			data lacking
Reproductive Toxicity:			conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:	Muta. 2	H341: Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.	
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:	Affected organs: Route of exposure:		data lacking
Specific target organ toxicity – repeated exposure:	Affected organs: Route of exposure:		conclusive but not sufficient for classification

Table 3.6. Classification and labelling according to CLP / GHS for the environment

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification

Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 2	H411: Toxic to aquatic life with long lasting effects.	
M-Factor acute:			
M-Factor chronic:			
Hazardous to the ozone layer:			conclusive but not sufficient for classification

Signal word: Danger

Hazard pictogram:

Figure 3.5.



GHS07: exclamation mark

Figure 3.6.



GHS09: environment

Figure 3.7.



GHS02: flame

Figure 3.8.



GHS03: flame over circle

Figure 3.9.



GHS08: health hazard

Hazard statements:

H251: Self-heating: may catch fire.

H272: May intensify fire; oxidiser.

H317: May cause an allergic skin reaction.

H341: Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H411: 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 label before use.

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P220: Keep away from clothing or other combustible materials.

P221: Take any precaution to avoid mixing with combustibles...

P235+P410: Keep cool. Protect from sunlight.

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

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.

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

P308+P313: IF exposed or concerned: Get medical advice/attention.

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

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

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

P370+P378: In case of fire: Use... to extinguish.

P391: Collect spillage.

P405: Store locked up.

P407: Maintain air gap between stacks or pallets.

P413: Store bulk masses greater than ... kg/... lbs at temperatures not exceeding ...°C/...°F.

P420: Store separately.

P501: Dispose of contents/container to ... …in accordance with local/regional/national /international regulations (to be specified). Manufacturer/supplier or the competent authority to specify whether disposal requirements apply to contents, container or both.

Substance: Diammonium hexakis(nitrito-N)rhodate - 'high impurity'

Implementation: EU

Related composition: Boundary Composition - 'high impurity'

The substance is classified as follows:

Table 3.7. Classification and labelling according to CLP / GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement	Reason for no classification
Explosives:			conclusive but not sufficient for classification
Desensitised explosives:			data lacking
Flammable gases and chemically unstable gases:			conclusive but not sufficient for classification
Flammable aerosols:			conclusive but not sufficient for classification
Oxidising gases:			conclusive but not sufficient for classification
Gases under pressure:			conclusive but not sufficient for

			classification
Flammable liquids:			conclusive but not sufficient for classification
Flammable solids:			conclusive but not sufficient for classification
Self-reactive substances and mixtures:			conclusive but not sufficient for classification
Pyrophoric liquids:			conclusive but not sufficient for classification
Pyrophoric solids:			conclusive but not sufficient for classification
Self-heating substances and mixtures:	Self Heat. 1	H251: Self-heating: may catch fire.	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification
Oxidising liquids:			conclusive but not sufficient for classification
Oxidising solids:	Oxid. Solid 3	H272: May intensify fire; oxidiser.	
Organic peroxides:			conclusive but not sufficient for classification
Corrosive to metals:			conclusive but not sufficient for classification

Table 3.8. Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:			conclusive but not sufficient for classification
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:			conclusive but not sufficient for classification
Serious damage / eye irritation:			conclusive but not sufficient for classification
Respiratory sensitisation:			data lacking
Skin sensitisation:	Skin Sens. 1	H317: May cause an allergic skin reaction.	
Aspiration hazard:			data lacking
Reproductive Toxicity:	Repr. 1A	H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.	
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:	Muta. 2	H341: Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.	

Carcinogenicity:	Carc. 1A	H350: May cause cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.	
Specific target organ toxicity – single exposure:	Affected organs: Route of exposure:		data lacking
Specific target organ toxicity – repeated exposure:	STOT Rep. Exp. 2 Affected organs: Causes damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion. Route of exposure: Oral and Inhalation	H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.	

Table 3.9. Classification and labelling according to CLP / GHS for the environment

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 2	H411: Toxic to aquatic life with long lasting effects.	
M-Factor acute:			
M-Factor chronic:			
Hazardous to the ozone layer:			conclusive but not sufficient for classification

Signal word: Danger

Hazard pictogram:

Figure 3.10.



GHS07: exclamation mark

Figure 3.11.



GHS09: environment

Figure 3.12.



GHS02: flame

Figure 3.13.



GHS03: flame over circle

Figure 3.14.



GHS08: health hazard

Hazard statements:

H251: Self-heating: may catch fire.

H272: May intensify fire; oxidiser.

H317: May cause an allergic skin reaction.

H341: Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H350: May cause cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H411: 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 label before use.

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P220: Keep away from clothing or other combustible materials.

P221: Take any precaution to avoid mixing with combustibles...

P235+P410: Keep cool. Protect from sunlight.

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

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

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.

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

P308+P313: IF exposed or concerned: Get medical advice/attention.

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

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

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

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

P370+P378: In case of fire: Use... to extinguish.

P391: Collect spillage.

P405: Store locked up.

P407: Maintain air gap between stacks or pallets.

P413: Store bulk masses greater than ... kg/... lbs at temperatures not exceeding ...°C/...°F.

P420: Store separately.

P501: Dispose of contents/container to ... …in accordance with local/regional/national /international regulations (to be specified). Manufacturer/supplier or the competent authority to specify whether disposal requirements apply to contents, container or both.

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

For rhodium, the log Kd for suspended matter is 4.18 (Kd is 15100) and the log Kd for soil is 0.58 (Kd 3.8).

Additional information:

Two high quality studies have determined the partitioning of Rh between river water and suspended particulate matter (Cobelo-Garcia et al. 2008, Turner et al. 2006). One high quality study assessed the partitioning of rhodium in two soils and one sediment (Sako et al. 2009).

Biodegradation and hydrolysis are not relevant for this substance as it is inorganic.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

No relevant information available.

Data waiving

Information requirement: Hydrolysis

Reason: study scientifically not necessary / other information available

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

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available.

4.1.1.2.2. Phototransformation in water

No relevant information available.

4.1.1.2.3. Phototransformation in soil

No relevant information available.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

No relevant information available.

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the ready biodegradability study does not need to be conducted as the substance is inorganic.

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

No relevant information available.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

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

Table 4.1. Studies on adsorption/desorption

Method	Results	Remarks
adsorption / desorption: screening batch equilibrium method Laboratory study, no guideline followed. Water samples were spiked with metals and shaken for 48 hours, followed by fractionation using 0.45 µm filtration. Rh concentrations were determined in the aqueous and solid phases by ICP-MS.	Adsorption coefficient: log Kd: 4.18 at 23°C (Mean for all salinities, standard deviation 0.43) log Kd: 4.1 at 23°C (Mean for freshwaters, standard deviation 0.51) log Kd: 4.27 at 23°C (Mean for estuarine waters, standard deviation 0.13) log Kd: 4.57 at 23°C (Single value for	2 (reliable with restrictions) key study experimental study **Test material** Rhodium (III) **Reference** Cobelo-Garcia A, Turner A, Millward G. 2008

	seawater, salinity 33 %)	
adsorption / desorption: screening	Adsorption coefficient: log Kd: 4.18 at 23°C (Mean for all salinities, standard deviation 0.43) log Kd: 4.1 at 23°C (Mean for freshwaters, standard deviation 0.51) log Kd: 4.27 at 23°C (Mean for estuarine waters, standard deviation 0.13) log Kd: 4.57 at 23°C (Single value for seawater, salinity 33 %)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Rhodium (III) **Reference** Cobelo-Garcia A, Turner A, Millward G. 2008

Justification for type of information:

1. HYPOTHESIS FOR THE ANALOGUE APPROACH

For risk assessment of metals it is not always possible to differentiate between the particular metal substances when conducting environmental monitoring and therefore exposure assessment for rhodium (III) substances is conducted based on total emissions of rhodium. This is a worst-case approach as emissions of all rhodium substances are combined and taken into consideration when determining the Predicted Environmental Concentration of rhodium (III), that is used in the risk assessment. The PNEC used in the risk assessment is also determined based on a worst-case approach as it is derived based on data for the most toxic rhodium (III) substance. As the risk assessment is conducted to cover all rhodium substances, a single Kd value for rhodium is used to model the partitioning of rhodium once released to the environment. The actual form of rhodium that is present in the environment following release of different rhodium substances is unknown and using different Kd values for each rhodium substance is not practical or necessarily relevant for risk assessment. One set of Kd values for rhodium (III) are therefore considered more appropriate for use in risk assessment.

2. SOURCE AND TARGET CHEMICAL(S)

Source chemical: Rhodium (III)

Target chemical: Diammonium sodium hexakis(nitrito-N)rhodate

3. ANALOGUE APPROACH JUSTIFICATION For risk assessment purposes, total measured rhodium concentrations in the environment are used in order to assess environmental exposure. The risk assessment conducted does not differentiate between rhodium (III) substances but covers all emissions of rhodium (III) substances from a site. As rhodium emissions are assessed together, Kd values for rhodium (III) and not for individual rhodium substances are relevant.		
adsorption / desorption: screening batch equilibrium method Laboratory study, no guideline followed. Sediment was added to river water samples, which were spiked with metals and shaken for up to 96 hours, followed by fractionation using 0.45 µm filtration. Rh concentrations were determined in the aqueous and solid phases by ICP-MS. Experiments were performed on samples of untreated, chemically reduced, and chemically oxidised sediment material.	Adsorption coefficient: log Kd: >4.2 - <4.9 at 20°C (Dependent on treatment of the sediment material.)	2 (reliable with restrictions) supporting study experimental study **Test material** Rhodium (III) **Reference** Turner A, Crussell M, Millward G, Cobelo-Garcia A, Fisher A 2006
adsorption / desorption: screening	Adsorption coefficient: log Kd: >4.2 - <4.9 at 20°C (Dependent on treatment of the sediment material.)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Rhodium (III) **Reference** Turner A, Crussell M, Millward G, Cobelo-Garcia A, Fisher A 2006

Justification for type of information: 1. HYPOTHESIS FOR THE ANALOGUE APPROACH For risk assessment of metals it is not always possible to differentiate between the particular metal substances when conducting environmental monitoring and therefore exposure assessment for rhodium (III) substances is conducted based on total emissions of rhodium. This is a worst-case approach as emissions of all rhodium substances are combined and taken into consideration when determining the Predicted Environmental Concentration of rhodium (III), that is used in the risk assessment. The PNEC used in the risk assessment is also determined based on a worst-case approach as it is derived based on data for the most toxic rhodium (III) substance. As the risk assessment is conducted to cover all rhodium substances, a single Kd value for rhodium is used to model the partitioning of rhodium once released to the environment. The actual form of rhodium that is present in the environment following release of different rhodium substances is unknown and using different Kd values for each rhodium substance is not practical or necessarily relevant for risk assessment. One set of Kd values for rhodium (III) are therefore considered more appropriate for use in risk assessment. 2. SOURCE AND TARGET CHEMICAL(S) Source chemical: Rhodium (III) Target chemical: Diammonium sodium hexakis(nitrito-N)rhodate 3. ANALOGUE APPROACH JUSTIFICATION For risk assessment purposes, total measured rhodium concentrations in the environment are used in order to assess environmental exposure. The risk assessment conducted does not differentiate between rhodium (III) substances but covers all emissions of rhodium (III) substances from a site. As rhodium emissions are assessed together, Kd values for rhodium (III) and not for individual rhodium substances are relevant.		
adsorption / desorption: screening batch equilibrium method Laboratory study, no guideline followed. Soil or sediment samples were spiked with metals and shaken for 24 hours, followed by fractionation using centrifugation and 0.45 µm filtration. Rh concentrations were determined in the aqueous and solid phases by ICP-MS.	Adsorption coefficient: log Kd: 0.58 at 25°C (Overall mean, standard deviation 0.38)	2 (reliable with restrictions) key study experimental study **Test material** Rhodium (III) **Reference** Sako A, Lopes L, Roychoudhury A 2009
adsorption / desorption: screening	Adsorption coefficient:	2 (reliable with

	log Kd: 0.58 at 25°C (Overall mean, standard deviation 0.38)	restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Rhodium (III) **Reference** Sako A, Lopes L, Roychoudhury A 2009

Justification for type of information:

1. HYPOTHESIS FOR THE ANALOGUE APPROACH

For risk assessment of metals it is not always possible to differentiate between the particular metal substances when conducting environmental monitoring and therefore exposure assessment for rhodium (III) substances is conducted based on total emissions of rhodium. This is a worst-case approach as emissions of all rhodium substances are combined and taken into consideration when determining the Predicted Environmental Concentration of rhodium (III), that is used in the risk assessment. The PNEC used in the risk assessment is also determined based on a worst-case approach as it is derived based on data for the most toxic rhodium (III) substance. As the risk assessment is conducted to cover all rhodium substances, a single Kd value for rhodium is used to model the partitioning of rhodium once released to the environment. The actual form of rhodium that is present in the environment following release of different rhodium substances is unknown and using different Kd values for each rhodium substance is not practical or necessarily relevant for risk assessment. One set of Kd values for rhodium (III) are therefore considered more appropriate for use in risk assessment.

2. SOURCE AND TARGET CHEMICAL(S)

Source chemical: Rhodium (III)

Target chemical: Diammonium sodium hexakis(nitrito-N)rhodate

3. ANALOGUE APPROACH JUSTIFICATION

For risk assessment purposes, total measured rhodium concentrations in the environment are used in order to assess environmental exposure. The risk assessment conducted does not differentiate

between rhodium (III) substances but covers all emissions of rhodium (III) substances from a site. As rhodium emissions are assessed together, Kd values for rhodium (III) and not for individual rhodium substances are relevant.

Discussion

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

For rhodium, the log Kd for suspended matter is 4.18 (Kd is 15100). The log Kd for soil is 0.58 (Kd 3.8).

Value used for CSA:

Other adsorption coefficients:

log Kp (solids-water in suspended matter): 4.18 at 23°C

log Kp (solids-water in soil): 0.58 at 25°C

Additional information:

Two high quality studies have determined the partitioning of Rh between river water and suspended particulate matter (Cobelo-Garcia et al. 2008, Turner et al. 2006). Cobelo-Garcia et al. (2008) showed variation in partitioning for freshwaters, and Kd values were slightly affected by salinity, with a trend of increasing partitioning with increasing salinity. A mean log Kd of 4.18 (stdev 0.43) was observed for all salinities, a mean log Kd of 4.10 (stdev 0.51) was observed for freshwaters only, a mean log Kd of 4.27 (stdev 0.13) was observed for estuarine waters only, and a single log Kd of 4.57 was determined in seawater (salinity 33 ‰). The supporting study (Turner et al 2006) showed that experiments with Rh were at, or close to, steady state within 96 hours, and exhibited moderate changes in adsorption following chemical reduction or chemical oxidation of the sediment particles, indicating the role of metal(oxy)hydroxides to be more important than organic matter in Rh partitioning. Log Kd values of between 4.2 and 4.9 were derived, depending upon the treatment of the sediment material. The Kd values for Rh determined in the two studies were similar, and the mean log Kd value for all salinities of 4.18 (Kd 15100), taken from Cobelo-Garcia et al. (2008), will be used in the risk assessment.

Sako et al. (2009) studied the partitioning of rhodium in two soils and one sediment. Although a standard guideline was not followed, the study is well described and meets generally accepted scientific methods. Kd values were reported at eight different metal concentrations, Freundlich adsorption model parameters were also reported as well as rate constants for adsorption and desorption. In order to account for the variability in Rh partitioning between different systems the overall mean (n=48, ± standard deviation) log Kd value will be used in the risk assessment, 0.58 ±0.38 for Rh.

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

For rhodium, the log Kd for suspended matter is 4.18 (Kd is 15100). The log Kd for soil is 0.58 (Kd 3.8).

Additional information:

Two high quality studies have determined the partitioning of Rh between river water and suspended particulate matter (Cobelo-Garcia et al. 2008, Turner et al. 2006). One high quality study assessed the partitioning of rhodium in two soils and one sediment (Sako et al. 2009).

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

No relevant information available.

4.4. Secondary poisoning

Based on the available information the bioaccumulation potential cannot be judged (see CSR chapter 7.6 “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:
Diammonium sodium hexakis(nitrito-N)rhodate is likely to be appreciably absorbed and rapidly excreted after administration by the oral route, based on limited experimental insights and extensive bio-elution in simulated gastric fluid. As such, predicted oral absorption is set at 100%.

Although exposure by the inhalation route is anticipated to be low, based on limited experimental data inhalation absorption is potentially extensive. In line with ECHA guidance, a conservative assumption of 100% inhalation absorption is proposed.

Significant bioavailability after dermal exposure is unlikely, given the low dermal penetration expected for metals and the observed lack of skin irritation potential. A value of 10% dermal absorption is proposed.

Once absorbed, distribution and excretion are expected to be rapid, with little or no bioaccumulation anticipated. 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 (%): 10
Absorption rate - inhalation (%): 100

Additional information:
Absorption
No good-quality information on oral absorption of rhodium compounds was identified. One report

noted that organic salts of rhodium “can be absorbed by the gastro-intestinal tract”, but quantitative absorption data were not given (Iavicoli et al., 2013). In general, a compound needs to be dissolved before it can be taken up from the gastro-intestinal tract after oral administration. Based on expert ECHA guidance, the relatively low molecular weight (~440 g/mol) and, more critically, the moderate water solubility (0.76 g/L; Gregory, 2014) are indicative of a high bioavailability of diammonium sodium hexakis(nitrito-N)rhodate, as ions, by this route. Furthermore, in a bio-elution test the proportion of metal release (from total metal content) in simulated gastric fluid was extensive (115%) after 2 hours (Rodriguez, 2012). A health-precautionary assumption is that the ions will be absorbed from the gastro-intestinal tract. As such, predicted oral absorption of diammonium sodium hexakis(nitrito-N)rhodate is set at 100%.

No good-quality data were found regarding absorption of rhodium compounds following inhalation. One report noted that organic salts of rhodium may be absorbed via inhalation following occupational exposure, but quantitative absorption data were not given (Iavicoli et al., 2013). Particle size distribution (PSD) data, as measured by simple sieving, indicate that only a small proportion (0.696%) of diammonium sodium hexakis(nitrito-N)rhodate is <100 µm (Tremain and Atwal, 2011). Dustiness testing, a more energetic PSD measurement, with the compound returned a mass median aerodynamic diameter (MMAD) value of 29.0 µm (Parr, 2011; Selck and Parr, 2011). An MMAD value <100 µm indicates that a significant proportion of the substance is likely to be inhalable. However, respiratory tract deposition modelling with the dustiness data yielded output values of 47.6, 0.20 and 0.32% for the nasopharyngeal (head), tracheobronchial (TB) and pulmonary regions of the respiratory tract, respectively. This indicates that little airborne substance (<1%) will be deposited in the lower regions of the human respiratory tract, i.e. the TB or pulmonary regions via oronasal normal augmenter breathing.

Most of the inhaled fraction is likely to be retained in the head region and therefore would be cleared by ingestion, along with that deposited in the TB region, and oral bioavailability will again predominantly determine systemic uptake. Only 0.32% is likely capable of reaching the alveoli. Thus, inhalation will not be a significant route of exposure. However, as a moderately water soluble substance, any diammonium sodium hexakis(nitrito-N)rhodate reaching the lungs is likely to be absorbed through aqueous pores or be retained in the mucus and transported out of the respiratory tract.

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

No good-quality data were found regarding absorption following dermal exposure to rhodium

compounds. The moderate water solubility suggests that diammonium sodium hexakis(nitrito-N)rhodate may be able to cross the lipid-rich environment of the stratum corneum to a “moderate to high” extent, indicating that the appropriate default value for dermal absorption is 100% in this case (ECHA, 2014). However, specific expert guidance on the health risk assessment of metals states that “inorganic compounds require dissolution involving dissociation to metal cations prior to being able to penetrate skin by diffusive mechanisms” and, as such, dermal absorption might be assumed to be very low (values of 0.1 and 1.0% are suggested for dry and wet media, respectively) (ICMM, 2007). Furthermore, there is no evidence that the substance causes skin irritation (which could facilitate a greater degree of dermal uptake) (Kiss, 2012a). In bio-elution tests with diammonium sodium hexakis(nitrito-N)rhodate, the proportion of metal release (from total metal content) in simulated dermal fluid was 15.95% and 38.4% after 24 and 168 hours, respectively (Rodriguez, 2012). Overall, it is suitably health precautionary to take forward the lower of the two ECHA default values for dermal absorption, of 10%.

Distribution/Metabolism

Once absorbed, distribution of ammonium/sodium and hexakis(nitrito-N)rhodate ions throughout the body is expected based on a relatively low molecular weight (~440 g/mol).

A combined repeated dose and reproductive/developmental toxicity dietary study in rats on diammonium sodium hexakis(nitrito-N)rhodate found changes in the lungs, kidney, pancreas and thymus (Török-Bathó, 2015), suggesting possible distribution to these organs.

Elimination (and Bioaccumulation)

In rats treated orally with Rhodium trichloride for 14 days, absorbed rhodium was mainly excreted through the urinary system (Iavicoli et al., 2013).

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, diammonium sodium hexakis(nitrito-N)rhodate is considered to have only a low potential for bioaccumulation based on its predicted physico-chemical properties (i.e. water solubility of 0.76 g/L).

Conclusion

Based on the physico-chemical properties, the chemical structure, molecular weight and the results of toxicity studies, as well as limited insights on organic rhodium salts, it can be assumed that diammonium sodium hexakis(nitrito-N)rhodate is likely partially bioavailable by the oral route and rapidly excreted once absorbed. Although inhalation is not anticipated to be a significant route of exposure (based on respiratory tract deposition modelling data), absorption could be extensive. A high dermal bioavailability is unlikely.

Absorption values of 100%, 10% and 100% are proposed for the oral, dermal and inhalation routes,

respectively, and are considered health-precautionary for use in the calculation of DNEL values.

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] (CRL:(WI) rats) female oral: gavage according to OECD Guideline 425 (Acute Oral Toxicity: Up-and-Down Procedure) ; according to EPA OPPTS 870.1100 (Acute Oral Toxicity)	LD50: >2000 mg/kg bw (female) based on: (test mat.) (CL not applicable)	1 (reliable without restriction) key study experimental study **Test material** 64164-17-6 / 264-713-0; Diammonium Sodium Hexakis (nitrito-N) Rhodate, Form: solid: particulate/powder **Reference** Matting E 2014

5.2.1.2. Acute toxicity: inhalation

No relevant information available.

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: other justification

Justification: - In accordance with Column 2 of REACH Annex VIII, this study does not need to be conducted as human exposure via inhalation of aerosols, particles or droplets of an inhalable size is unlikely. Particle size distribution (PSD) data, as measured by simple sieving, indicate that 0.696% of diammonium sodium hexakis(nitrito-N)rhodate is <100 µm (Tremain and Atwal, 2011). Dustiness testing, a more energetic PSD measurement, with the compound returned a mass

median aerodynamic diameter (MMAD) value of 29.0 µm (Parr, 2011; Selck and Parr, 2011). An MMAD value <100 µm indicates that a significant proportion of a substance is likely to be inhalable. Respiratory tract deposition modelling with the dustiness data yielded output values of 47.6, 0.20 and 0.32% for the nasopharyngeal (head), tracheobronchial (TB) and pulmonary regions of the respiratory tract, respectively. Hence, very little airborne substance (<1%) is expected to deposit in the lower regions of the human respiratory tract, i.e. the TB or pulmonary regions via oronasal normal augmenter breathing. Most of the inhaled fraction is likely to be retained in the head region and could be coughed or sneezed out of the body or swallowed, with systemic uptake being determined predominantly by oral bioavailability. Thus, inhalation will not be a significant route of exposure. Further, diammonium sodium hexakis(nitrito-N)rhodate is classified as a germ cell mutagen (category 2), and is allocated to the “high” hazard band (for systemic effects following inhalation exposure). Consequently, appropriate safety labelling, personal protection and RMMs/OCs will be in place, ensuring that the potential for inhalation exposure is strictly controlled. As such, there are sufficient available data for chemical hazard and risk assessment, classification and labelling, and risk mitigation purposes. Finally, for animal welfare reasons, conducting new in vivo toxicity tests is considered a last resort. Consequently, no testing by the inhalation route is considered justified.

5.2.1.3. Acute toxicity: dermal

No relevant information available.

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: other justification

Justification: - In accordance with Column 2 of REACH Annex VIII, this study does not need to be conducted as the substance does not meet the criteria for classification for acute toxicity by the oral route. Moreover, the existing skin sensitisation study (Henzell, 2013), albeit limited in its assessment of general systemic toxicity, indicates a lack of acute systemic toxicity following dermal exposure. Exposure considerations also provide good support for the conclusion that an acute dermal toxicity study can be waived. First, skin contact during production and/or use is expected to be very low. Second, diammonium sodium hexakis(nitrito-N)rhodate is classified for germ cell mutagenicity (category 2) and is allocated to the “high” hazard band (for systemic effects following dermal exposure). Consequently, appropriate safety labelling, personal protection and RMMs/OCs will be in place, ensuring that the potential for dermal exposure is strictly controlled. As such, there are sufficient available data for chemical hazard and risk assessment, classification and labelling, and risk mitigation purposes. Finally, for animal welfare reasons, conducting new in vivo toxicity tests is considered as a last resort. Consequently, no testing by the dermal route is considered justified.

5.2.1.4. Acute toxicity: other routes

No relevant information available.

5.2.2. Human information

No relevant information available.

5.2.3. Summary and discussion of acute toxicity

The following information is taken into account for any hazard / risk assessment:
In an OECD guideline study, the acute oral LD50 value for diammonium sodium hexakis(nitrito-N)rhodate was determined to exceed 2000 mg/kg bw following gavage administration in female rats.

No relevant acute dermal or inhalation toxicity data were identified.

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

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

The acute oral toxicity of diammonium sodium hexakis(nitrito-N)rhodate was assessed in female rats, in a study carried out in accordance with OECD Test Guideline 425 and to GLP. Animals were treated by gavage with the test material (in 1% methyl cellulose) at doses of 175 (1 animal), 550 (1 animal) or 2000 (3 animals) mg/kg body weight. Macroscopic examination was conducted on surviving animals. No mortality, clinical signs or effects on body weight/growth were apparent during the 14-day post-dose observation period, and there were no notable external or internal macroscopic findings upon necropsy. The study investigators concluded that the acute oral median lethal dose (LD50) of diammonium sodium hexakis(nitrito-N)rhodate was greater than 2000 mg/kg bw in female rats (Matting, 2014).

No acute inhalation toxicity data were identified. However, 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, no acute dermal toxicity data were identified. However, this study does not need to be conducted as the substance does not meet the criteria for

classification for acute toxicity by the oral route.

Justification for classification or non classification:
Based on the results of the available and reliable acute oral rat study, diammonium sodium hexakis(nitrito-N)rhodate does not require classification for acute oral toxicity according to EU CLP criteria (EC 1272/2008).

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

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

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

Table 5.2. Studies on skin irritation

Method	Results	Remarks
human [other species] (Reconstructed human epidermis model (see details below)) Coverage: Applied evenly to the epidermal surface following the application of 10 ul distilled water to this surface (in vitro cell culture) Vehicle: water - distilled according to OECD Guidelines for Testing of Chemicals, Section 4, No. 439, “In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method” adopted 22 July 2010 ; according to EpiSkin™ SOP, Version 1.8 (February 2009), ECVAM Skin Irritation Validation Study: Validation of the EpiSkin™ test method 15 min - 42 hours for the prediction of acute skin irritation of chemicals. Available at: [http://ecvam.jrc.ec.europa.eu] ;	GHS criteria not met other: Value: 68 (- Basis: mean Cell/tissue viability. Time point: 42 hours. Reversibility: other: Not applicable. Remarks: Score is a percentage (%) of negative control. Mean relative viability <=50% the test substance is considered to be irritant to skin.	1 (reliable without restriction) key study experimental study **Test material** 64164-17-6 / 264-713-0 **Reference** Kiss I 2012a

according to IN VITRO SKIN IRRITATION: RECONSTRUCTED HUMAN EPIDERMIS MODEL TEST in relation to Regulation (EC) No 440/2008 (as amended) and Regulation (EC) No 1907/2006 on REACH (Annex III, B.46).		

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

5.3.1.2. Human information

No relevant information available.

5.3.2. Eye

5.3.2.1. Non-human information

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

Table 5.3. Studies on eye irritation

Method	Results	Remarks
rabbit (New Zealand White [rabbit]) Vehicle: unchanged (no vehicle) according to OECD Guideline 405 (Acute Eye Irritation / Corrosion) ; according to EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion) ; according to EPA OPPTS 870.2400 (Acute Eye Irritation)	GHS criteria not met chemosis score - Conjunctival chemosis (mean - of all 3 animals) 0 of max. 4 (Time point: Mean of 24, 48 and 72-hour timepoints) Not applicable Slight chemosis was seen in one animal at one hour; this had resolved by 24 hours Conjunctival discharge (mean) 0 of max. 3 (Time point: Mean of 24, 48 and 72-hour timepoints) Not applicable Considerable discharge was seen in one animal, and slight discharge in two animals, at 1 hour; this had	1 (reliable without restriction) key study experimental study **Test material** 64164-17-6 / 264-713-0 **Reference** Kiss I 2012c

	resolved to normal by 24 hours in all cases Conjunctival redness (mean) 0.56 of max. 3 (Time point: Mean of 24, 48 and 72-hour timepoints) fully reversible - 1 week One animal was symptom-free by 24 hours, one by 72 hours and one by 1 week cornea opacity score - opacity, degree of density (mean) 0 of max. 4 (Time point: Mean of 24, 48 and 72-hour timepoints) Not applicable No corneal opacity was seen in any animal at any time point iris score (mean) 0 of max. 2 (Time point: Mean of 24, 48 and 72-hour timepoints) Not applicable The iris was not affected in any animal at any time point	
in vitro study Chicken (isolated eyes only) (ROSS 308) Vehicle: None according to OECD guideline 438 The Enucleated Eye Test with isolated eyes of chickens has been recognized as a valuable alternative to the Draize eye irritation test, because it represents a test system nearest to the in vivo test, without the need to use live animals. In the Isolated	Does not require classification as a severe eye irritant percent corneal swelling - up to 75 min mean of three values; value 0 percent corneal swelling - up to 240 min mean of three values; value 1 cornea opacity score mean of three values; value 0 fluorescein retention score mean of three values; value 0.5	1 (reliable without restriction) supporting study experimental study **Test material** 64164-17-6 / 264-713-0 **Reference** Kiss I 2012d

Chicken Eye Test (ICET) the test compound is applied in one single dose onto the cornea of isolated eyes, which are obtained from slaughter animals. This method can provide detailed information about the effects of test items on the cornea, and is useful to compare products, to classify test items for regulatory use when they are severe irritants or corrosive to the eye, and thus to avoid the need to test severe eye irritants in vivo. The test is described in OECD 438 and is approved by international regulatory agencies as a replacement for the identification of corrosives and severe irritants in the in vivo Rabbit eye assay (OECD 405).		

Data waiving

Information requirement: Eye Irritation

Reason: study scientifically not necessary / other information available

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

5.3.2.2. Human information

No relevant information available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No relevant information available.

5.3.3.2. Human information

No relevant information available.

5.3.4. Summary and discussion of irritation

The following information is taken into account for any hazard / risk assessment:
In two in vitro reconstructed human epidermis (EpiSkin) assays, conducted in accordance with OECD Test Guidelines 431 and 439 (for assessing skin corrosion and irritation, respectively) and to GLP, diammonium sodium hexakis(nitrito-N)rhodate was considered to be neither corrosive nor irritating to skin (Kiss, 2012a,b).

In an OECD Test Guideline 405 study, to GLP, diammonium sodium hexakis(nitrito-N)rhodate (0.1 g) caused some conjunctival effects in the eyes of three male rabbits within 1 hr of instillation, but these effects were fully reversible within 1 week (Kiss, 2012c).

No relevant respiratory tract irritation data were identified.

Value used for CSA:
Skin irritation / corrosion: no adverse effect observed (not irritating)
Eye irritation: no adverse effect observed (not irritating)
Respiratory irritation: no study available

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

Diammonium sodium hexakis(nitrito-N)rhodate was tested for skin corrosion and irritation potential in two EpiSkin (in vitro reconstructed human epidermis model) assays conducted in accordance with OECD Test Guidelines 431 and 439, respectively, and to GLP. EpiSkin is a three-dimensional human skin model comprising a reconstructed epidermis with a functional stratum corneum. Its use for skin irritation testing involves topical application of test materials to the surface of the epidermis, and the subsequent assessment of their effects on cell viability, as determined by cellular mitochondrial dehydrogenase activity. The reduction of cell viability in treated tissues is compared to negative controls and expressed as a %. In the test for skin corrosion, following a 4-hour exposure to the test substance, the test system skin cell viability was calculated to be greater than 35% (the average was 72% and the range was 69 -75%), and it was therefore considered to be non-corrosive to skin. In the skin irritation test, following a 15-minute exposure to the test substance, the test system skin cell viability was calculated to be greater than 50% (the average was 68% and the range was 60-76%), and it was therefore considered to be non-irritating to skin (Kiss, 2012a,b).

In an in vitro eye irritation study in isolated chicken eyes, conducted in accordance with OECD Test Guideline 438, diammonium sodium hexakis(nitrito-N)rhodate appeared to be not severely irritating/corrosive and does not require a classification as a severe eye irritant. However, this test substance remained adhered to the corneal surface after the post-treatment rinse (Kiss, 2012d). As such, an in vivo study is required to determine classification (see below).

In an in vivo eye irritation study carried out in accordance with OECD Test Guideline 405, and to GLP, 0.1 g of powdered diammonium sodium hexakis(nitrito-N)rhodate was instilled into the conjunctival sac of one eye of 3 male New Zealand White rabbits. Following instillation the eyelids were held closed for several seconds; no rinsing was performed. The other eye remained untreated and was used for control purposes. The eyes were examined at 1, 24, 48, 72 hours, as well as 1 week after treatment, and scored according to the Draize system. Mild conjunctival effects (including redness, chemosis and discharge) occurred within one hour of application. These were either reduced or absent at 24 hours and were fully reversible within 1 week (Kiss, 2012c).

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

Justification for classification or non classification:
Based on the results of the available (in vitro) skin corrosion and irritation studies and the (in vivo and in vitro) eye irritation studies, diammonium sodium hexakis(nitrito-N)rhodate does not require classification for skin or eye irritation 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 5.4. Studies on skin irritation related to corrosivity

Method	Results	Remarks
Tissue studied: skin corrosion: in vitro / ex vivo human [other species] (Reconstructed human epidermis model (see details below)) Coverage: Applied evenly to the epidermal surface before the	Non-corrosive to skin other: Value: 72 (- Basis: mean Cell/tissue viability. Time point: 4 hours. Reversibility: other: Not applicable. Remarks: Score is a percentage (%) of negative control. Mean relative	1 (reliable without restriction) key study experimental study **Test material** 64164-17-6 / 264-713-0

application of 10 ul NaCl solution. (in vitro cell culture) Vehicle: physiological saline according to OECD Guidelines for Testing of Chemicals, Section 4, No. 431, “In Vitro Skin Corrosion: Human Skin Model” adopted 13 April 2004 ; according to Commission Regulation (EC) No 440/2008, Annex Part B, B.40Bis: “IN VITRO SKIN CORROSION: HUMAN SKIN MODEL TEST”, Official Journal of the European Union No. L142, dated May 31st, 2008.	viability <=35% the test substance is considered to be corrosive to skin.	**Reference** Kiss I 2012b

5.4.2. Human information

No relevant information available.

5.4.3. Summary and discussion of corrosion

The studies with results indicating corrosivity are discussed in section 5.3.4 Summary and discussion of irritation.

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

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

Table 5.5. Studies on skin sensitisation

Method	Results	Remarks
mouse (CBA/Ca (CBA/CaOlaHsd)) female skin sensitisation: in vivo (LLNA)	GHS criteria not met Stimulation index: (See Table 1 in “any other information on results incl.	2 (reliable with restrictions) key study

according to OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay) ; according to EU Method B.42 (Skin Sensitisation: Local Lymph Node Assay) ; according to EPA OPPTS 870.2600 (Skin Sensitisation)	tables".) disintegrations per minute (DPM): (See Table 1 in "any other information on results incl. tables".)	experimental study **Test material** 64164-17-6 / 264-713-0, Form: solid - liquid: suspension **Reference** Henzell G 2013

Data waiving

Information requirement: Skin Sensitisation

Reason: study scientifically not necessary / other information available

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

5.5.1.2. Human information

No relevant information available.

5.5.2. Respiratory system

5.5.2.1. Non-human information

No relevant information available.

5.5.2.2. Human information

No relevant information available.

5.5.3. Summary and discussion of sensitisation

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

Skin sensitisation

Diammonium sodium hexakis(nitrito-N)rhodate was non-sensitising in a mouse local lymph node assay (LLNA), conducted according to OECD Test Guideline 429 and to GLP (Henzell, 2013).

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

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

The skin sensitising potential of diammonium sodium hexakis(nitrito-N)rhodate was assessed in a mouse LLNA conducted in accordance with OECD Test Guideline 429 and to GLP. Following a preliminary test using a concentration of 25% w/w, female CBA/Ca mice (5/group) received 25 µL applications of the test material, in propylene glycol at 0, 5, 10 or 25%, to the skin of both ears for three consecutive days. Two additional groups of 5 females were respectively treated with propylene glycol alone and phenylacetaldehyde, a known sensitiser, at 2.5%. Mice were monitored for mortality and overt signs of toxicity, as well as changes in body weight. Three days after the induction period (on day six), mice were given tail vein injections of radiolabelled thymidine, and were sacrificed after approximately five hours. Lymph nodes were excised and processed for radioactivity. No signs of skin irritation or systemic toxicity were observed in the preliminary test. In the main experiment, SI values were 1.19, 0.96 and 1.36 for animals given respective concentrations of 5%, 10% and 25%. An SI value of over 3 was judged to be indicative of a substance being sensitising. Hence, under the conditions of this assay, diammonium sodium hexakis(nitrito-N)rhodate was considered non-sensitising (Henzell, 2013).

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

Respiratory sensitisation

Value used for CSA: no study available

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

Justification for classification or non classification:
Based on the results of the available and reliable murine LLNA assay, diammonium sodium hexakis(nitrito-N)rhodate does not warrant classification for skin sensitisation, according to EU CLP criteria (EC 1272/2008).

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of studies are summarised in the following table:

Table 5.6. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks
rat [common rodent species] (Wistar [rat]) male/female short-term repeated dose toxicity: oral (oral: gavage) 100mg/kg bw/day (nominal) 300mg/kg bw/day (nominal) 1000mg/kg bw/day (nominal) Vehicle: methylcellulose - 1% in distilled water Exposure: 28 days for males (14 days pre-mating and 14 days mating/post-mating period); 52-54 days for females (14 days pre-mating, for up to 12 days of the mating period, through gestation (22-24 days) and up to and including the day before necropsy (at least 4 days post-partum dosing). (Daily) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	NOAEL: 1000 mg/kg bw/day (nominal) (male/female) based on: (test mat.) No treatment-related adverse effects were noted on general toxicology parameters	1 (reliable without restriction) key study experimental study **Test material** Diammonium Sodium Hexakis (nitrito-N) Rhodate / 64164-17-6, Form: solid: particulate/powder **Reference** Török-Bathó M 2015

5.6.1.2. Repeated dose toxicity: inhalation

No relevant information available.

5.6.1.3. Repeated dose toxicity: dermal

No relevant information available.

5.6.1.4. Repeated dose toxicity: other routes

No relevant information available.

5.6.2. Human information

No relevant information available.

5.6.3. Summary and discussion of repeated dose toxicity

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

Key Information:

In an OECD Test Guideline 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of diammonium sodium hexakis(nitrito-N)rhodate for at least 28 days, no treatment-related adverse effects were observed at up to the highest tested dose (1000 mg/kg bw/day) (Török-Bathó, 2015).

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

Value used for CSA (via oral route - systemic effects):

no adverse effect observed (NOAEL : 1000mg/kg bw/day) (subacute ; rat [common rodent species])

Value used for CSA (inhalation - systemic effects):

no study available

Value used for CSA (inhalation - local effects):

no study available

Value used for CSA (dermal - systemic effects):

no study available

Value used for CSA (dermal - local effects):

no study available

Additional information:

No relevant human data were identified.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, Wistar rats (12/sex/group in the main test) were orally administered diammonium sodium hexakis(nitrito-N)rhodate by stomach tube (gavage) at doses of 0 (vehicle control), 100, 300 or 1000 mg/kg bw/day. Males were dosed for 28 days (14 days pre-mating and 14 days through the mating and post-mating periods). Main test females were dosed for 14 days pre-mating, through mating (up to 12 days), gestation (22-24 days) and up to post-partum day 5 (around 7 weeks in total). Additional females (5/group), assigned to satellite groups for toxicology endpoints, were treated for 28 days. Daily gavage administration of diammonium sodium hexakis(nitrito-N)rhodate to rats did not result in test item related mortality, clinical signs of toxicity, neurological (including FOB) or ophthalmoscopy observations, or changes in the body weight, food consumption, haematology, clinical chemistry or urinalysis parameters at dose levels of up to 1000 mg/kg bw/day. There were no adverse treatment-related changes in organ weights, or following macroscopic and microscopic examination of a wide range of tissues and organs for the adult animals of either sex. On this basis, a study NOAEL of 1000 mg/kg bw/day was established (Török-Bathó, 2015).

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:
No adverse systemic effects were seen in a reliable repeated dose toxicity study (combined with a reproductive/developmental screening assay) following gavage administration of diammonium sodium hexakis(nitrito-N)rhodate to rats for at least 28 days. As such, classification of diammonium sodium hexakis(nitrito-N)rhodate as STOT-RE is not required, according to EU CLP criteria (EC 1272/2008).

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

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

Table 5.7. The results of in vitro genotoxicity studies are summarised in the following table:

Method	Results	Remarks
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria] (Met. act.: with and without) Test concentrations: Range-Finder Experiment and Mutation Experiment 1 (with and without S9) 5 16 50 160 500 1600 5000 ug/plate Mutation Experiment 2 (with and without S9) 160 300 625 1250 2500 5000 ug/plate Mutation Experiment 2 Additional work in strain TA100 (without S9) 500 1000 2000 3000 4000 5000 ug/plate Mutation Experiment 2 Additional work in strain TA1537 (without S9) 100 250 750 1000 1250 2500 5000 ug/plate Positive control substance(s): 9-aminoacridine ; 2-nitrofluorene ; sodium azide ; benzo(a)pyrene ; mitomycin C ; 2-aminoanthracene according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	Test results: negative - Expt 2 treatment in TA1537 produced a notable increase in revertants at the highest non-precipitating concentration. This was considered not to be a mutagenic effect (see below). for S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria]; met. act.: with and without genotoxicity: negative - Expt 2 treatment in TA1537 produced a notable increase in revertants at the highest non-precipitating concentration. This was considered not to be a mutagenic effect (see below). cytotoxicity: yes - Or a maximum test concentration of 5 mg/plate. vehicle controls valid: yes negative controls valid: yes positive controls valid: yes Remark: all strains/cell types tested	2 (reliable with restrictions) key study experimental study **Test material** 64164-17-6 / 264-713-0; Rhodium nitrite salt, Form: solid: particulate/powder **Reference** McGarry S 2014
mammalian cell gene mutation assay [gene mutation] (in vitro gene mutation study in mammalian cells - Type of genotoxicity: gene mutation) mouse lymphoma L5178Y cells [mammalian cell line] (Met. act.: with and without)	Test results: negative for mouse lymphoma L5178Y cells [mammalian cell line]; met. act.: with and without genotoxicity: negative cytotoxicity: no, but tested up to precipitating concentrations	1 (reliable without restriction) key study experimental study **Test material** 64164-17-6 / 264-713-0, Form: solid:

Test concentrations: Range-finder: 0, 46.88, 93.75, 187.5, 375, 750 and 1500 ug/mL, considered to be the limit at which the stock formulation was homogeneous and did not fall out of suspension. Experiment 1: ten concentrations, ranging from 50 to 1200 ug/mL, with and without S-9. Experiment 2: ten concentrations, ranging from 50 to 1000 ug/mL, with and without S-9. Positive control substance(s): 4-nitroquinoline-N-oxide ; benzo(a)pyrene according to OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) [in vitro gene mutation study in mammalian cells]	vehicle controls valid: yes negative controls valid: not applicable positive controls valid: yes Remark: all strains/cell types tested	particulate/powder **Reference** Lloyd M 2014a
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study - Type of genotoxicity: other: chromosome damage) Chinese hamster Ovary (CHO) [mammalian cell line] (Met. act.: with and without) Test concentrations: In range-finder experiment, treatments “3+21” in the presence and absence of S9 and “24+0” in the absence of S9: 3.628 to 1000 ug/ml The following represent the test concentrations for which the results were statistically evaluated. A wider range was actually tested, but the results were not subject to analysis. In experiment 1, treatments “3+21” in the absence of S9: 400 800	Test results: negative - Small statistically significant increase in mean MNBN cell frequency at highest dose; within historical control range and considered of no biological relevance. for Chinese hamster Ovary (CHO) [mammalian cell line]; met. act.: without genotoxicity: negative - Small statistically significant increase in mean MNBN cell frequency at highest dose; within historical control range and considered of no biological relevance. cytotoxicity: yes vehicle controls valid: yes negative controls valid: not examined positive controls valid: yes Remark: other: 3+21 hour treatment	2 (reliable with restrictions) key study experimental study **Test material** 64164-17-6 / 264-713-0; Rhodium nitrite salt, Form: solid: particulate/powder **Reference** Lloyd M 2014b

1100 1300 ug/ml In experiment 1, treatments “3+21” in the presence of S9: 200 600 1100 1300 ug/ml In experiment 1, treatment “24+0” in the absence of S9: 150 300 400 ug/ml In experiment 2, treatment “24+0” in the absence of S9: 200 250 300 350 ug/ml Positive control substance(s): cyclophosphamide ; mitomycin C ; vinblastine according to OECD guideline 487: In Vitro Mammalian Cell Micronucleus Test	Test results: ambiguous - Statistically significant increase in MNBN cells at highest concentration. Data were considered inconclusive and a second, confirmatory experiment, was performed under this treatment condition. for Chinese hamster Ovary (CHO) [mammalian cell line]; met. act.: without genotoxicity: ambiguous - Statistically significant increase in MNBN cells at highest concentration. Data were considered inconclusive and a second, confirmatory experiment, was performed under this treatment condition. cytotoxicity: yes vehicle controls valid: yes negative controls valid: not examined positive controls valid: yes Remark: other: 24+0 hour treatment, experiment 1 Test results: negative for Chinese hamster Ovary (CHO) [mammalian cell line]; met. act.: without genotoxicity: negative cytotoxicity: yes vehicle controls valid: yes negative controls valid: not examined positive controls valid: yes Remark: other: 24+0 hour treatment, experiment 2 Test results: negative for Chinese hamster Ovary (CHO) [mammalian cell line]; met. act.: with genotoxicity: negative cytotoxicity:	

	yes vehicle controls valid: yes negative controls valid: not examined positive controls valid: yes Remark: other: 3+21 hour treatment	

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 a bacterial reverse mutation (Ames) test, conducted according to OECD Test Guideline 471 and to GLP, diammonium sodium hexakis(nitrito-N)rhodate failed to induce an increase in mutation frequency in five histidine-requiring Salmonella typhimurium strains (TA98, TA100, TA1535, TA1537 and TA102) when tested at concentrations of up to 5000 µg/plate or up to the limit of cytotoxicity, in the absence and presence of S9 (McGarry, 2014).

In an in vitro mammalian cell gene mutation assay, conducted in accordance with OECD Test Guideline 476 and to GLP, diammonium sodium hexakis(nitrito-N)rhodate did not induce biologically relevant increases in mutation at the hprt locus in mouse lymphoma L5178Y cells when tested up to precipitating concentrations in the absence and presence of S9 (Lloyd, 2014a).

In an in vitro micronucleus assay, conducted according to OECD Test Guideline 487 and to GLP, diammonium sodium hexakis(nitrito-N)rhodate failed to induce biologically relevant increases in micronuclei in Chinese hamster ovary cells when tested up to the limit of cytotoxicity, for 3 hours in the absence and presence of S9, and for 24 hours without S9 (Lloyd, 2014b).

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

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

vivo):
No in vivo genotoxicity data were identified.

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

Additional information:
Diammonium sodium hexakis(nitrito-N)rhodate was tested in a bacterial reverse mutation (Ames) assay, conducted according to OECD Test Guideline 471 and to GLP. The test substance was assayed in five histidine-requiring strains (TA98, TA100, TA1535, TA1537 and TA102) of S. typhimurium, both in the absence and in the presence of metabolic activation by an Aroclor 1254-induced rat liver post-mitochondrial fraction (S9), in two separate experiments. The highest concentrations of test article analysed were up to 5000 µg/plate or up to the limit of cytotoxicity and were determined following a preliminary toxicity range-finder experiment. In experiment 2, treatments in the presence of S9 included a pre-incubation step. Appropriate vehicle and positive control cultures were included in the test system under each treatment condition and fit the acceptance criteria. Following treatments of all the test strains in the absence and presence of S9, only Experiment 2 treatments in strain TA1537 in the absence of S9 at 1250 µg/plate (the highest non-precipitating concentration) resulted in an increase in revertant numbers that was ≥3-fold the concurrent control. The increase was small in magnitude and occurred at a single intermediate concentration with no clear indication of a concentration relationship or reproducibility between experiments. Accordingly this was not considered evidence of mutagenic activity. Following Experiment 2 treatments in strain TA100 in the absence of S9, some of the untreated control revertant colony counts were higher than the historical control ranges and increases of 1.6-fold the concurrent vehicle controls were observed. In order to confirm if these increases were due to normal biological variability or mutagenicity, Experiment 2 additional treatments were performed in this strain; no increases were observed that were ≥2-fold the concurrent vehicle controls. It is concluded that diammonium sodium hexakis(nitrito-N)rhodate did not induce mutation in five histidine-requiring strains (TA98, TA100, TA1535, TA1537 and TA102) of S. typhimurium when tested at concentrations up to 5000 µg/plate or up to the limit of toxicity, in the absence and in the presence of S9 (McGarry, 2014).

In an in vitro GLP study, conducted in accordance with OECD Test Guideline 476 (in vitro mammalian cell gene mutation assay), diammonium sodium hexakis(nitrito-N)rhodate was tested for its ability to induce gene mutations at the hprt locus in mouse lymphoma L5178Y cells. In a cytotoxicity range finding study, six concentrations (46.88-1500 µg/mL) were tested (with and without S9); precipitation was seen after 3 hours incubation at the two highest concentrations, with and without S9. The main test consisted of two experiments, each using an incubation time of 3 hours and testing 10 concentrations with and without S9. Precipitation was observed at the end of the incubation period in both experiments: above 400 µg/mL (Experiment 1) and above 300 µg/mL (Experiment 2), with and without S9 in both cases. In Experiment 1, small but statistically significant increases in mean mutant frequency (MF) over the concurrent vehicle control value were observed at two intermediate

concentrations (250 and 350 µg/mL) in the absence of S9. However, these values were less than three times the historical mean vehicle control value and this effect was not observed at higher doses (there was no statistically significant linear trend). Moreover, the increases were not reproducible as in the absence of S9 in Experiment 2. Therefore, the small, sporadic increases in MF seen in the absence of S9 in Experiment 1 were considered of little or no biological relevance. In the presence of S9 when tested up to precipitating concentrations, no statistically significant increases in mean MF were observed at any concentration analysed in Experiments 1 and 2 and there were no significant linear trends. Overall, diammonium sodium hexakis(nitrito-N)rhodate did not induce biologically relevant increases in gene mutations at the hprt locus of L5178Y mouse lymphoma cells when tested up to cytotoxic concentrations in two independent experiments in the absence and presence of S9 (Lloyd, 2014a).

Diammonium sodium hexakis(nitrito-N)rhodate was tested for its ability to induce chromosome damage (micronuclei) in Chinese hamster ovary cells in an assay conducted in accordance with OECD Test Guideline 487 and to GLP. The highest concentrations of test article analysed were limited by toxicity and were determined following a preliminary cytotoxicity range-finder experiment. Cells were treated with the test material (in 1% methyl cellulose) for either 3 hours (with 21 hours recovery time), or for 24 hours, up to cytotoxic concentrations in the absence (24-hour treatments) or presence and absence (3-hour treatments) of S9. Appropriate vehicle and positive control cultures were included in the test system under each treatment condition and matched the acceptance criteria. Treatment of cells with diammonium sodium hexakis(nitrito-N)rhodate for 3 hours and for 24 hours in the absence of S9 resulted in frequencies of micronucleated binucleate MNBN cells that were generally similar to (marginally but not significantly higher than) those observed in concurrent vehicle controls at the various concentrations analysed under both treatment conditions. A statistically significant increase in micronuclei was observed at the highest concentration (1300 µg/mL) in the 3-hour treatment in the absence of S9, but the effect was small and the frequency of micronucleated cells was well within the historical control range. A statistically significant increase in micronuclei was also observed at the highest-tested concentration (400 µg/mL) in one of two experimental runs of the 24-hour treatment (without S9), but this effect was found to be not reproducible in a similar experiment (also conducted in duplicate but up to a slightly less cytotoxic concentration). As a result, neither of these changes was considered biologically relevant. Overall, diammonium sodium hexakis(nitrito-N)rhodate did not induce biologically relevant increases in the frequency of micronuclei in Chinese hamster ovary cells treated in culture, when tested up to the limit of cytotoxicity in the presence and absence (3-hour treatment) or absence (24-hour treatment) of S9 (Lloyd, 2014b).

Justification for classification or non classification

Based on the existing data set, diammonium sodium hexakis(nitrito-N)rhodate does not currently meet the criteria for classification as a germ cell mutagen (category 1A or 1B) under EU CLP criteria (EC 1272/2008). However, in spite of the negative results following in vitro genotoxicity testing, based

on the anticipated speciation of diammonium sodium hexakis(nitrito-N)rhodate in vivo (dissociation and binding with chloride ligands in the gastric environment), the substance is classified as a category 2 mutagen on a precautionary basis.

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

No relevant information available.

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

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

Table 5.8. Studies on fertility

Method	Results	Remarks
rat (Wistar [rat]) male/female screening for reproductive / developmental toxicity oral: gavage 100mg/kg bw/day (nominal) 300mg/kg bw/day (nominal) 1000mg/kg bw/day (nominal) Vehicle: methylcellulose - 1% in distilled water Exposure: 28 days for males (14 days pre-mating and 14 days mating/post-mating period) and satellite females; 52-54 days for females (14 days pre-mating, for up to 12 days of the mating period, through gestation (22-24 days) and up to and including the day before necropsy (at least 4 days post-partum dosing). (Daily) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	**First parental generation (P0)** NOAEL (PO) 1000 mg/kg bw/day (nominal)) (male/female) based on: No treatment-related adverse general systemic or reproductive effects seen at highest tested dose **Second parental generation (P1)** **F1 generation** NOAEL (PO): 1000 mg/kg bw/day (nominal) (male/female) based on: No developmental effects seen at highest tested dose	1 (reliable without restriction) key study experimental study **Test material** Diammonium Sodium Hexakis (nitrito-N) Rhodate / 64164-17-6, Form: solid: particulate/powder **Reference** Török-Bathó M 2015

5.9.1.2. Human information

No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

No relevant information available.

5.9.2.2. Human information

No relevant information available.

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

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

In an OECD Test Guideline 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of diammonium sodium hexakis(nitrito-N)rhodate for at least 28 days, no treatment-related adverse effects on any measured reproductive or fertility parameters were observed. The systemic and reproductive NOAEL was the highest tested dose (1000 mg/kg bw/day) (Török-Bathó, 2015).

Value used for CSA (route: oral):

no adverse effect observed (NOAEL) 1000mg/kg bw/day (subacute ; rat [common rodent species])

Value used for CSA (route: dermal):

no study available

Value used for CSA (route: inhalation):

no study available

Additional information:

No relevant data in humans were identified.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, Wistar rats (12/sex/group in the main test) were orally administered diammonium sodium hexakis(nitrito-N)rhodate by stomach tube (gavage) at doses of 0 (vehicle control), 100, 300 or 1000 mg/kg bw/day. Males were dosed for 28 days (14 days pre-mating and 14 days through the mating and post-mating periods). Main test females were dosed for 14 days pre-mating, through mating (up to 12 days), gestation (22-24 days) and up to post-partum day 5 (around 7 weeks in total). There were no reported changes to reproductive parameters (including number of corpora lutea, implantation sites, number of pups, fertility and gestation indices, reproductive performance as well as pre- and post-implantation losses). The systemic and reproductive NOAEL was the highest tested dose (1000 mg/kg bw/day) (Török-Bathó, 2015).

Developmental toxicity

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

In an OECD Test Guideline 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of diammonium sodium hexakis(nitrito-N)rhodate for at least 28 days, no developmental effects were observed. The systemic and developmental NOAEL was the highest tested dose (1000 mg/kg bw/day) (Török-Bathó, 2015).

Value used for CSA (route: oral):

no adverse effect observed (NOAEL) 1000mg/kg bw/day (subacute ; rat [common rodent species])

Value used for CSA (route: dermal):

no study available

Value used for CSA (route: inhalation):

no study available

Additional information:

No relevant data in humans were identified.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, Wistar rats (12/sex/group in the main test) were orally administered diammonium sodium hexakis(nitrito-N)rhodate by stomach tube (gavage) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for 28 days (14 days pre-mating and 14 days through the mating and post-mating periods). Main test females were dosed for 14 days pre-mating, through mating (up to 12 days), gestation (22-24 days) and up to post-partum day 5 (around 7 weeks in total). There were no adverse effects on the F1 offspring viability, clinical signs or developmental effects. The systemic and developmental NOAEL was the highest tested dose (1000 mg/kg bw/day) (Török-Bathó, 2015).

Justification for classification or non classification:

No adverse effects on reproductive parameters (sexual function or fertility) or development of offspring were seen in a reliable guideline combined repeated dose toxicity study and reproductive/developmental toxicity screening study with diammonium sodium hexakis(nitrito-N)rhodate. As such, classification of diammonium sodium hexakis(nitrito-N)rhodate for reproductive toxicity is not required, according to EU CLP criteria (EC 1272/2008).

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.

5.10.2. Human information

No relevant information available.

5.10.3. Summary and discussion of other effects

No relevant information available.

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

5.11.1. Overview of typical dose descriptors for all endpoints

Table 5.9. Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type
Acute toxicity	oral	no adverse effect observed
Acute toxicity	dermal	no study available
Acute toxicity	inhalation	no study available
Irritation / Corrosivity	skin	no adverse effect observed (not irritating)

Irritation / Corrosivity	eye	no adverse effect observed (not irritating)
Irritation / Corrosivity	resp. tract	no study available
Sensitisation	skin	no adverse effect observed (not sensitising)
Sensitisation	resp. tract	no study available
Repeated dose toxicity	oral	no adverse effect observed (NOAEL): 1000 mg/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): 1000 mg/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): 1000 mg/kg bw/day (subacute; rat

		[common rodent species])
Reproductive toxicity: developmental toxicity	dermal	no study available
Reproductive toxicity: developmental toxicity	inhalation	no study available

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

Table 5.10. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	high hazard (no threshold derived)	genetic toxicity
Inhalation	Systemic effects - Acute	no hazard identified	
Inhalation	Local effects - Long-term	no hazard identified	
Inhalation	Local effects - Acute	no hazard identified	
Dermal	Systemic effects - Long-term	high hazard (no threshold derived)	genetic toxicity
Dermal	Systemic effects - Acute	no hazard identified	
Dermal	Local effects - Long-term	no hazard identified	
Dermal	Local effects - Acute	no hazard identified	

Eyes	Local effects	no hazard identified	

Discussion:

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

Diammonium sodium hexakis(nitrito-N)rhodate showed no evidence of genotoxicity in vitro (Lloyd, 2014a,b; McGarry, 2014). No substance-specific in vivo genotoxicity data were identified. However, on a precautionary basis, the substance is self-classified as a category 2 mutagen based on its anticipated speciation in vivo; this is anticipated to involve decomposition and dissolution in the gastric environment to form chloro-aqua Rh(III) species. This is a similar behaviour to rhodium trichloride which has a positive in vivo micronucleus test (Rodrigo, 2007) and is self-classified as Muta. 2).

This implies that assessing the risk of exposure to diammonium sodium hexakis(nitrito-N)rhodate via inhalation to human health, from a quantitative DNEL based on the findings of a short-term repeated dose toxicity study, may not be protective. A DMEL approach is arguably more appropriate. However, since no adequate studies assessing carcinogenicity were available for the substance, no robust DMEL can be calculated. Although the use of read across, subchronic studies or the threshold of toxicological concern (TTC) concept may be explored as alternatives in such a derivation, no specific ECHA guidance is available for these approaches (ECHA, 2012a). Moreover, no suitable read-across candidates or subchronic studies were identified and the TTC concept is not applicable to inorganic compounds. Consequently, based on the mutagenicity classification, the most appropriate and health precautionary approach was deemed to be to formulate a qualitative assessment (with ‘high hazard’ banding and recommended RMMs/OCs in Table E.3-1 of ECHA, 2012b) for systemic exposure to workers by inhalation. (It is anticipated that this qualitative approach with its associated stringent RMMs/OC requirements “will likely be sufficient to also cover for other relevant effects for which DNELs can be derived, for all routes of exposure”). However, to ensure that this qualitative assessment is appropriate, a quantitative DNEL approach has also been evaluated (see below).
As no relevant data on effects of repeated inhalation exposure to diammonium sodium hexakis(nitrito-N)rhodate in laboratory animals are available, route-to-route extrapolation to calculate an inhalation DNEL from a reliable combined repeated-dose with reproductive/developmental toxicity screening study by the oral route was considered a suitable alternative (particularly as first pass effects are not expected to be significant for an inorganic compound).

In a guideline (OECD TG 422) combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of diammonium sodium hexakis(nitrito-N)rhodate for at least 28 days, no clinical signs of toxicity or any adverse pathological or histopathological effects were observed. No test item-related microscopic changes were noted in the reproductive organs. Moreover, no effects on reproductive parameters or indications of

maternal/foetal toxicity were observed at any dose level. Thus, the NOAEL for systemic, reproductive and developmental toxicity was the highest tested dose (1000 mg/kg bw/day) (Török-Bathó, 2015). This equates to a NOAEL of 234.99 mg/kg bw/day when expressed as elemental rhodium based on MWt ratios[1], and is considered protective of fertility and developmental toxicity.

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

Corrected inhalatory NOAEC (worker, 8 h exposure/day) = oral NOAEL*(1/sRv[rat])*(ABS[oral-rat]/ABS[inh-human]) *(sRV[human]/wRV) = 1000 mg/kg bw/day*(1/0.38 m^3/kg bw/day)*(1/2)*(6.7 m^3 [8h]/10 m3 [8h]) = 881.6 mg/m^3

It is noted that the standard respiratory rate conversion figure (0.38 m^3/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 no metabolism of inorganic metal complexes is anticipated to occur in vivo. It is therefore considered appropriate to increase the corrected inhalatory NOAEC by a factor of 4.

Dose descriptor starting point (after route to route extrapolation) = Corrected inhalatory NOAEC (worker, 8 h exposure/day)*4 = 881.6*4 = 3526 mg/m^3

Application of the appropriate assessment factors (overall AF 75)[2] to this corrected inhaled NOAEC gives a systemic long-term inhalation DNEL for diammonium sodium hexakis(nitrito-N)rhodate of 47.0 mg/m^3. This equates to an elemental rhodium exposure of 11.0 mg/m^3.

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

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

[1] MWts: Rh metal, 102.9 g mol-1; Diammonium sodium hexakis(nitrito-N)rhodate, 437.9 g mol-1

[2] Comprising AFs of 1 (for dose response relationship: default ECHA AF for the use of a NOAEL from a well-conducted combined repeated-dose with reproductive/developmental toxicity screening study), 6 (for differences in duration of exposure: default ECHA AF for subacute [28-day] to chronic extrapolation), 1 (for interspecies differences [allometric scaling]: default ECHA AF for rat for toxicokinetic differences in metabolic rate is not required), 2.5 (for other interspecies differences: default ECHA AF for remaining toxicokinetic differences [not related to metabolic rate] and toxicodynamic differences), 5 (for intraspecies differences: default ECHA AF for [healthy] worker), 1 (for the quality of the whole database: default ECHA AF since the human health effects data are reliable and consistent, and confidence in the database is high) and 1 (for remaining uncertainties).

There are no data in relation to acute inhalation or dermal exposure to diammonium sodium hexakis(nitrito-N)rhodate. In a guideline (OECD TG 423) acute oral toxicity study in female rats, the LD50value was found to exceed 2000 mg/kg bw (Matting, 2014). The compound is not classified for acute oral toxicity according to CLP criteria.

"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, diammonium sodium hexakis(nitrito-N)rhodate is not classified for acute toxicity according to CLP, so a qualitative assessment is not required.

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

There are no data in relation to respiratory tract irritation or sensitisation of diammonium sodium hexakis(nitrito-N)rhodate in humans or laboratory animals. Consequently, no worker-DNELs for long-term or acute local effects in the respiratory tract have been calculated. Further, the substance is not classified as a skin irritant or skin sensitiser.

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

Diammonium sodium hexakis(nitrito-N)rhodate showed no evidence of genotoxicity in vitro (Lloyd, 2014a,b; McGarry, 2014); no substance-specific in vivo genotoxicity data were identified. However, on a precautionary basis, the substance is self-classified as a category 2 mutagen based on its anticipated speciation in vivo; this is anticipated to involve decomposition and dissolution in the gastric environment to form chloro-aqua Rh(III) species. This is a similar behaviour to rhodium trichloride which has a positive in vivo micronucleus test (Rodrigo, 2007) and is self-classified as Muta. 2).

This implies that assessing the risk of exposure to diammonium sodium hexakis(nitrito-N)rhodate by the dermal route to human health, from a quantitative DNEL based on the findings of a short-term repeated dose toxicity study, may not be protective. A DMEL approach is arguably more appropriate. However, since no adequate studies assessing carcinogenicity were available for the substance, no robust DMEL can be calculated. Although the use of read across, subchronic studies or the TTC concept may be explored as alternatives in such a derivation, no specific ECHA guidance is available for these approaches (ECHA, 2012a). Moreover, no suitable read-across candidates or subchronic studies were identified and the TTC concept is not applicable to inorganic compounds. Consequently, based on the mutagenicity classification, the most appropriate and health precautionary approach was deemed to be to formulate a qualitative assessment (with 'high hazard' banding and recommended RMMs/OCs in Table E.3-1 of ECHA, 2012b) for systemic exposure to workers by the dermal route. (It is anticipated that this qualitative approach with its associated stringent RMMs/OC

requirements “will likely be sufficient to also cover for other relevant effects for which DNELs can be derived, for all routes of exposure”). However, to ensure that this qualitative assessment is appropriate, a quantitative DNEL approach has also been evaluated (see below).

As no relevant data on effects of repeated dermal exposure to diammonium sodium hexakis(nitrito-N)rhodate in humans or laboratory animals are available, route-to-route extrapolation to calculate a dermal DNEL from a reliable combined repeated-dose with reproductive/developmental toxicity screening study by the oral route was considered a suitable alternative (particularly as first pass effects are not expected to be significant for an inorganic compound). This study has already been described above [“Hazard via inhalation route: systemic effects following long-term exposure”] (Török-Bathó, 2015).
The oral NOAEL of 1000 mg/kg bw/day equates to a NOAEL of 234.99 mg/kg bw/day for elemental rhodium (based on MWt ratios), and is considered protective of fertility and developmental toxicity.

This derivation has utilised REACH guidance. In order to make the most health-precautionary derivation, the worst-case scenario is obtained by the minimum absorption by the ‘starting’ route. However, for this oral-to-dermal extrapolation, a figure of 100% oral absorption has been used based on bio-elution data in simulated gastric fluid (Rodriguez, 2012).

The analogous bio-elution (proportion of metal release from total metal content) of diammonium sodium hexakis(nitrito-N)rhodate in simulated dermal fluid was 15.95% and 38.4% after 24 and 168 hours, respectively (Rodriguez, 2012); no substance-specific dermal absorption data are available. However, an in vitro permeation study on a related rhodium salt, rhodium trichloride, indicated a low degree of dermal absorption [about 1.2%]. Using a RhCl3 solution (0.3 mg Rh/ml in synthetic sweat) and full thickness skin from four Caucasian females, 1.2% (as a mean value) diffused into the skin in 24 hr; the receptor solution contained a further 0.0001% (Franken et al., 2014). Apart from this study, very little information appears to be available regarding dermal absorption of rhodium compounds.

Overall, a high dermal bioavailability is unlikely, notably given the low dermal penetration expected for metals (ICMM, 2007) as well as experimental dermal penetration data (human in vitro study) for a related surrogate [indicating about 1.2% dermal absorption], and considering the observed lack of skin irritation potential (which could facilitate a greater degree of dermal uptake) (Kiss, 2012a). It is deemed suitably health precautionary to take forward the lower of the two ECHA (2014) default values for dermal absorption, 10%, for the current safety assessment.

Dose descriptor starting point (after route to route extrapolation) = NOAEL*(ABS[oral-rat]/ABS[der-human]) = 1000 mg/kg bw/day*(100%/10%) = 10,000 mg/kg bw/day.

Application of the appropriate assessment factors (overall AF 75, described above) to this corrected dermal NOAEL gives a systemic long-term dermal DNEL for diammonium sodium hexakis(nitrito-

N)rhodate of 133.3 mg/kg bw/day, which equates to an elemental rhodium exposure of 31.3 mg/kg bw/day.

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

In a guideline (OECD TG 439) in vitro skin irritation study with diammonium sodium hexakis(nitrito-N)rhodate, the test system skin cell viability was calculated to be greater than 50% and the compound was therefore not classified for skin irritation under CLP (Kiss, 2012a).

In another guideline (OECD TG 429) study, diammonium sodium hexakis(nitrito-N)rhodate failed to induce skin sensitisation in the mouse local lymph node assay (LLNA) at up to concentrations of 25% (Henzell, 2013). Consequently, the compound is not classified for skin sensitisation under CLP.

Hazard for the eyes

In a guideline (OECD TG 405) eye irritation study, diammonium sodium hexakis(nitrito-N)rhodate produced slight but reversible effects on the eye in rabbits (Kiss, 2012c). In a previously conducted in vitro isolated chicken eye irritation study (OECD TG 438), the substance was not severely irritating or corrosive (Kiss, 2012d). The compound is not classified for eye irritation under EU CLP.

Overall, diammonium sodium hexakis(nitrito-N)rhodate is not expected to present a hazard to the eyes of workers.

Table 5.11. Hazard conclusions for the general population

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

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

Discussion:

DNELs have been derived only for workers, not for consumers/general population. During assessment of the identified uses for diammonium sodium hexakis(nitrito-N)rhodate, no uses have been identified in which consumers are exposed to the substance. In all uses with potential consumer

exposure due to service life of articles, diammonium sodium hexakis(nitrito-N)rhodate is chemically transformed into another substance before reaching the consumers, and the subsequent lifecycle steps after this transformation are included in the assessment of the newly-formed substance. Regarding the general population, and following the criteria outlined in ECHA guidance R16 (2016), an assessment of indirect exposure of humans via the environment for diammonium sodium hexakis(nitrito-N)rhodate has not been performed as the registered substance is manufactured/imported/marketed at <100 tpa and is not classified in category 1 for CMR properties.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

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

Table 6.1. Information on explosivity

Method	Results	Remarks
explosive properties of explosives according to UN Manual of Tests and Criteria: Part I: Classification procedures, test methods and criteria relating to explosives of Class 1	Evaluation of results: Study results: Small-scale preliminary tests: sensitiveness to impact: impact energy (J): (negative (not further specified) - No explosions were observed up to the maximum impact energy applied of 50 J and the result is considered negative for the BAM fall hammer test for shock) sensitiveness to friction: friction load (N): (negative (not further specified) - No explosions were observed using the maximum friction load of 360 N and the result is considered negative for the BAM friction test) thermal sensitivity - Koenen test: diameter of the orifice plate: (positive (not further specified) - An explosion was observed with a limiting orifice diameter of 2mm) Remarks: The Koenen test specifies for the testing to be started using an orifice plate of 20mm and if no explosion occurs the diameter of the orifice to be reduced in a series of single trials (to a minimum diameter of 1mm) until an explosion occurs. However, it was decided to start	1 (reliable without restriction) key study experimental study **Test material** Diammonium sodium hexakis(nitrito-N)rhodate **Reference** Atwal SS Tremain SP 2011

	testing using a 1mm orifice plate because a limited amount of test item was available. For the same reason, the test item that was used to determine the amount of test item required to fill the tube to 15mm from the top, using three equal increments was re-used for packing the steel tube for test 1. As all tubes were filled to 15mm from the top using the same amount of test item and the specified amount of pressure for packing, this deviation is considered not to have any significance with regard to the result.	

Discussion

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

No explosions were observed up to the maximum impact energy applied of 50 J, and the result is considered negative for the BAM fall hammer test for shock; no explosions were observed using the maximum friction load of 360 N and the result is considered negative for the BAM friction test; an explosion was observed with a limiting orifice diameter of 2mm and the result is considered positive (diammonium sodium hexakis(nitrito-N)rhodate showed a violent effect on heating under confinement) for the Koenen test for thermal sensitivity.

Value used for CSA:

Explosiveness:

Additional information:

Atwal and Tremain (2011) is a GLP compliant study following standard test guidelines which is considered suitable for use as a key study for this endpoint.

No explosions were observed up to the maximum impact energy applied of 50 J, and the result is considered negative for the BAM fall hammer test for shock; no explosions were observed using the maximum friction load of 360 N and the result is considered negative for the BAM friction test; an explosion was observed with a limiting orifice diameter of 2mm and the result is considered positive (diammonium sodium hexakis(nitrito-N)rhodate showed a violent effect on heating under confinement) for the Koenen test for thermal sensitivity.

Classification according to GHS

Name: Diammonium hexakis(nitrito-N)rhodate - ‘high purity’

Related composition: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘high purity’ (solid: particulate/powder)

Classification: conclusive but not sufficient for classification

Name: Diammonium hexakis(nitrito-N)rhodate - ‘low impurity’

Related composition: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘low impurity’ (solid: particulate/powder)

Classification: conclusive but not sufficient for classification

Name: Diammonium hexakis(nitrito-N)rhodate - ‘high impurity’

Related composition: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘high impurity’ (solid: particulate/powder)

Classification: conclusive but not sufficient for classification

6.2. Flammability

Flammability

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

Table 6.2. Information on flammability

Method	Results	Remarks
flammable solids equivalent or similar to UN Manual of Tests and Criteria: Test N.1 (Test method for readily combustible solids)	Evaluation of results: GHS criteria not met Study results: Flammable solids: burning rate test: preliminary screening test (substance does not ignite and propagate combustion either by burning with flame or smouldering along 200 mm of the powder train within the 2 minutes test period)	1 (reliable without restriction) key study experimental study **Test material** Diammonium sodium hexakis(nitrito-N)rhodate **Reference** Atwal SS Tremain SP 2011

Discussion

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

Flammability

Key value for chemical safety assessment: Flammability: not classified

Diammonium sodium hexakis(nitrito-N)rhodate is not classified as a flammable solid under Division 4.1 as it failed to ignite in the preliminary screening test.

Additional information:

Atwal and Tremain (2011) is a GLP compliant study following UN method N1 and is considered suitable for use as the key study for this endpoint.

Diammonium sodium hexakis(nitrito-N)rhodate is not classified as a flammable solid under Division 4.1 as it failed to ignite in the preliminary screening test.

Flash Point

No relevant information available.

Data waiving: see CSR section 1.3 Physicochemical properties.

Discussion

Classification according to GHS

Name: Diammonium hexakis(nitrito-N)rhodate - 'high purity'

Related composition: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition 'high purity' (solid: particulate/powder)

Classification (gas): conclusive but not sufficient for classification

Classification (liquid): conclusive but not sufficient for classification

Classification (solid): conclusive but not sufficient for classification

Name: Diammonium hexakis(nitrito-N)rhodate - 'low impurity'

Related composition: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition 'low impurity' (solid: particulate/powder)

Classification (gas): conclusive but not sufficient for classification

Classification (liquid): conclusive but not sufficient for classification

Classification (solid): conclusive but not sufficient for classification

Name: Diammonium hexakis(nitrito-N)rhodate - 'high impurity'

Related composition: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition 'high impurity' (solid: particulate/powder)

Classification (gas): conclusive but not sufficient for classification

Classification (liquid): conclusive but not sufficient for classification

Classification (solid): conclusive but not sufficient for classification

Justification for classification or non-classification:

Diammonium sodium hexakis(nitrito-N)rhodate is not classified as a flammable solid under Division 4.1 as it failed to ignite in the preliminary screening test.

6.3. Oxidising potential

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

Table 6.3. Information on oxidising potential

Method	Results	Remarks
oxidising solids Contact with: powdered cellulose	Evaluation of results: Category 3 (oxidising solids) based on GHS criteria	1 (reliable without restriction)

equivalent or similar to UN Manual of Tests and Criteria: Test O.1 (Test for oxidizing solids)	Test results: Oxidising solids: 1:1 sample-to-cellulose ratio: mean burning time: 225 s (The burning time for test 1 was not recorded because the extinguishing of the flame was thought to be the end of the reaction, and thus the timing device was stopped at this point. It was not considered necessary to repeat test 1 as it was unlikely to affect the classification.) 4:1 sample-to-cellulose ratio: mean burning time: 90 s (The ignition broke during 4 of the 5 tests. The burning time for test 3 (where wire did not break) is reasonable typical of the burning times for the tests where the wire broke. This showed that the breaking of the wire did not have any significant effect on the burning times. The time for test 5 was not recorded prior to the wire breaking and the burning time was not recorded due to a timing device malfunctioning, however it was concluded that repeating the test was not necessary as it was unlikely to affect the classification.) Remarks: The test item was ground before use to allow for a reduction in particle size during handling and transport. Authors state that the burning time for test 1 for the 1:1 test item: cellulose mixture was not recorded because the extinguishing of the flame was thought to be the end of the reaction, timing device stopped at this point.	key study experimental study **Test material** Diammonium sodium hexakis(nitrito-N)rhodate **Reference** Atwal SS Tremain SP 2011

	The values of the current and voltage recorded for test 1 and 2 (4:1 test item: cellulose mixture) indicated a power dissipation of 158 and 199 watts respectively which is outside the method specification. However the author states this did not have a significant effect on burning times. The current for test 5 (4:1 test item: cellulose mixture) was not recorded prior to the wire breaking and the burning time was not recorded because of a timing device malfunction. The mode of burning for test 5 was typical of the other 4 tests and as the mean burning time of the other 4 test was approximately in the middle of the mean burning times of the two reference mixtures, it was concluded that repeating test 5 was unlikely to affect the classification of the test item with regard to oxidising properties.	

Discussion

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

Diammonium sodium hexakis(nitrito-N)rhodate is classified in Category 3 for oxidising solids in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on classification, Labelling and Packaging of Substances and Mixtures.

Value used for CSA:

Oxidising properties: oxidising

Additional information:

This is a GLP compliant study following UN method O1 (oxidising solids) which is considered suitable for use for this endpoint.

Diammonium sodium hexakis(nitrito-N)rhodate is classified in Category 3 for oxidising solids in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on classification, Labelling and Packaging of Substances and Mixtures.

Classification according to GHS

Name: Diammonium hexakis(nitrito-N)rhodate - ‘high purity’

Related composition: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘high purity’ (solid: particulate/powder)

Classification (gas): conclusive but not sufficient for classification

Classification (liquid): conclusive but not sufficient for classification

Classification (solid): Oxid. Solid 3 (Hazard statement: H272: May intensify fire; oxidiser.)

Name: Diammonium hexakis(nitrito-N)rhodate - ‘low impurity’

Related composition: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘low impurity’ (solid: particulate/powder)

Classification (gas): conclusive but not sufficient for classification

Classification (liquid): conclusive but not sufficient for classification

Classification (solid): Oxid. Solid 3 (Hazard statement: H272: May intensify fire; oxidiser.)

Name: Diammonium hexakis(nitrito-N)rhodate - ‘high impurity’

Related composition: Diammonium sodium hexakis(nitrito-N)rhodate - boundary composition ‘high impurity’ (solid: particulate/powder)

Classification (gas): conclusive but not sufficient for classification

Classification (liquid): conclusive but not sufficient for classification

Classification (solid): Oxid. Solid 3 (Hazard statement: H272: May intensify fire; oxidiser.)

Justification for classification or non-classification:

Diammonium sodium hexakis(nitrito-N)rhodate is classified in Category 3 for oxidising solids in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on classification, Labelling and Packaging of Substances and Mixtures.

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

Additional information:

Tests have been conducted with diammonium sodium hexakis(nitrito-N)rhodate for acute *Daphnia*, algae and toxicity to microorganisms endpoints. As *Daphnia* and algal results are similar for the two substances, and as algae are the most sensitive trophic level and will drive classification, it is considered appropriate to read across data for acute toxicity to fish from another rhodium(III) substance, rhodium trinitrate (hydrate).

The most sensitive trophic level is algae, with an E_rC50 of 4.5 mg test item L^{-1} and an E_rC10 of 0.313 mg L^{-1}, for diammonium sodium hexakis(nitrito-N)rhodate and these values are used for classification purposes.

For PNEC derivation all data for rhodium(III) substances has been pooled and the PNEC values derived based on the most sensitive result. In the risk assessment, emissions of different rhodium substances are not analysed separately and therefore measured environmental concentrations are available based on total rhodium concentrations. As the measured emissions data is not apportioned to a particular rhodium(III) substance, a single set of PNECs covering all rhodium substances in the same oxidation state is considered to be the most appropriate approach for conducting the risk assessment. For aquatic PNECs the lowest EC50 value is for the rhodium(III) substance rhodium(III) chloride. There is some indication that rhodium substances containing a chloro ligand may be more toxic than those without, and therefore using the value for rhodium trichloride as the key value for PNEC derivation for all rhodium(III) substances is likely to be worst case.

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
Cyprinus carpio freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test) ; according to EU Method C.1 (Acute Toxicity for Fish)	LC50 (96h): 116 mg/L test mat. (nominal) based on: mortality (- Range: 90 - 150 mg/L) LC50 (96h): 41.4 mg/L element (nominal) based on: mortality (LC50 based on rhodium concentration calculated from the data in the report	2 (reliable with restrictions) key study experimental study **Test material** Rhodium (III) nitrate hydrate

	based on a rhodium concentration of 35.7%)	**Reference** Enste-Diefenbach R. 2003
short-term toxicity to fish	LC50 (96h): 116 mg/L test mat. (nominal) based on: mortality (- Range: 90 - 150 mg/L) LC50 (96h): 41.4 mg/L element (nominal) based on: mortality (LC50 based on rhodium concentration calculated from the data in the report based on a rhodium concentration of 35.7%)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Rhodium (III) nitrate hydrate **Reference** Enste-Diefenbach R. 2003

Justification for type of information:
REPORTING FORMAT FOR THE ANALOGUE APPROACH

1. HYPOTHESIS FOR THE ANALOGUE APPROACH

Read across between metal compounds should take into account the oxidation state of the metal and the contribution of any potential toxicity due to the ligands. Both diammonium sodium hexakis(nitrito-N)rhodate and rhodium trinitrate (hydrate) are in the same oxidation state (Rh(III)). Both substances are also soluble and therefore likely to be available in the aquatic environment. Although there are differences in the ligands between the source and target substances, toxicity is considered to be attributed to rhodium(III), with the ligands not considered to contribute significantly to the toxicity of either substance.

There is some evidence from other precious metals that substances in which the metallic centre is coordinated with chloro ligands exhibit greater toxicity than substances with other types of ligands.

Toxicity to *Daphnia* and algae have been assessed for both substances in order to test the hypothesis that read across between the two substances is appropriate. Read across from rhodium trinitrate

(hydrate) to diammonium sodium hexakis(nitrito-N)rhodate is then proposed for the acute toxicity to fish endpoint.

2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES)

Source: Rhodium trinitrate (hydrate)
Target: Diammonium sodium hexakis(nitrito-N)rhodate

Please see attached Read Across Justification Report for discussion of impurities.

3. ANALOGUE APPROACH JUSTIFICATION

The read across hypothesis for fulfilling REACH data requirements is based on the source and target substances both containing rhodium in the same oxidation state, being available in the environment and having ligands that do not contribute additional toxicity. Available physico-chemical and ecotoxicity data for the two substances has been assessed in order to verify if the read across approach is acceptable.

Measured water solubility data shows that both substances are soluble (0.76 g L^{-1} for diammonium sodium hexakis(nitrito-N)rhodate and 1170 g L^{-1} for rhodium trinitrate (hydrate)). In the available ecotoxicity tests conducted with diammonium sodium hexakis(nitrito-N)rhodate measured concentrations were within 80% of nominal at test start and remained stable throughout the tests. In the acute fish study conducted with rhodium trinitrate (hydrate) measured concentrations at test start were also within 80% of nominal (apart from one sample which was significantly higher than nominal and therefore disregarded) and measured concentrations at the end of the 24-hour renewal period were also within 80% of nominal. Both substances are therefore considered to be available in the aquatic environment.

The inorganic ligands are not expected to impact on the toxicity of either substance. However, this was assessed by comparing test data for other acute ecotoxicity endpoints (*Daphnia* and algae). An acute *Daphnia* study was completed for diammonium sodium hexakis(nitrito-N)rhodate (Simon 2014). Based on the *Daphnia* data, the EC50 for diammonium sodium hexakis(nitrito-N)rhodate is lower than that for rhodium trinitrate (when expressed as concentrations of rhodium), although the confidence intervals of the two values overlap. There were also potential pH issues with the rhodium trinitrate *Daphnia* study and the EC50 reported may be lower than expected based on the test item toxicity alone. Read-across from rhodium trinitrate for the other ecotoxicity endpoints was thus uncertain

based on the *Daphnia* data, and an algal growth inhibition study with diammonium sodium hexakis(nitrito-N)rhodate was conducted (Wenzel 2015).

The results of the algal studies for the two substances were compared and were very similar. As the algal results for the two substances were similar this supports the hypothesis that the ligands do not contribute significantly to the toxicity of either test item, and toxicity can mainly be attributed to rhodium(III). It is therefore considered appropriate to read across the result from rhodium trinitrate (hydrate) for the toxicity to fish endpoint. There is some variability between the results for the two substances, particularly with the *Daphnia* results, but as fish are not the most sensitive trophic level (LC50 41.4 mg Rh L^{-1} for fish compared to E_rC50 of >0.32 mg Rh L^{-1} and E_bC50 of 0.31 mg Rh L^{-1} for algae) read across is considered to be appropriate for this endpoint as any potentially small difference in results between the two substances would not lead to a difference in environmental classification, which will be assigned based on the algal results.

Daphnia and algal results are similar for the two substances, and therefore the inorganic ligands are not considered to contribute significantly to the toxicity of either substance. Although there is some variability in the available ecotoxicity results, as algae are the most sensitive trophic level and will drive classification, it is considered to be appropriate to read across the acute toxicity to fish data in order to reduce the need for additional vertebrate testing. Acute toxicity to *Daphni*a and algal toxicity endpoints will be completed with data on the substance itself.

4. DATA MATRIX

Please see attached Read Across Justification Report.

Discussion

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

The 96 hour LC50 value, read across from rhodium trinitrate (hydrate) is 41.4 mg Rh L^{-1}.

Additional information:

Acute toxicity to fish data are read across from rhodium trinitrate (hydrate). Read across is considered to be appropriate for the acute fish endpoint as although there are differences in the ligands between the two substances, any toxicity is attributed to rhodium and both diammonium sodium hexakis(nitrito-N)rhodate and rhodium trinitrate (hydrate) are in the same oxidation state (Rh(III)). Although there is some variability in the *Daphnia* results between the two substances, as *Daphnia* and algal results are similar for the two substances, and as algae are the most sensitive trophic level and will drive classification, it is considered appropriate to read across data for acute toxicity to fish from another rhodium(III) substance, rhodium trinitrate (hydrate).

Enste-Diefenbach (2003) is a GLP compliant study and followed a standard guideline. However, pH values were outside the desired limit for this test and the two highest test concentrations were not used due to the very low pH. There was some evidence of undissolved test material in the 90 and 150 mg L^{-1} test solutions but the higher test concentrations were clear. No mortality was observed at 90 mg L^{-1}, and 100 % mortality was observed in the 150 and 260 mg L^{-1} test solutions. The LC50 value was therefore determined graphically. The 96h LC50 of Rhodium (III) nitrate hydrate is 116 mg L^{-1} (41.4 mg Rh L^{-1}). This study followed a standard test guideline but there were restrictions in the study design therefore it is assigned a Klimisch score of 2 (reliable with restrictions).

7.1.1.2. Long-term toxicity to fish

No relevant information available.

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 7.2. Short-term effects on aquatic invertebrates

Method	Results	Remarks
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for *Daphnia*)	EC50 (48h): 81.3 mg/L test mat. (nominal) based on: mortality (95% CL: 31.8-324.3 mg Rh/L) NOEC (48h): 45.5 mg/L test mat. (nominal) based on: mortality LOEC (48h): 100 mg/L test mat. (nominal) based on: mortality EC10 (48h): 28.3 mg/L test mat. (nominal) based on: mortality (95% CL: 0.4-56.3 mg Rh/L)	1 (reliable without restriction) key study experimental study **Test material** Diammonium sodium hexakis (nitrito-N) rhodate **Reference** Simon M 2014
Daphnia magna freshwater static according to OECD Guideline 202 (*Daphnia* sp. Acute Immobilisation Test)	EC50 (48h): 290 µg/L element (meas. (not specified)) based on: mobility	2 (reliable with restrictions) key study experimental study **Test material** Rhodium trichloride (hydrate) **Reference** Okamoto A,

		Yamamuro M, Tatarazako N 2014
	EC50 (48h): 290 µg/L element (meas. (not specified)) based on: mobility	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Rhodium trichloride (hydrate) **Reference** Okamoto A, Yamamuro M, Tatarazako N 2014

Justification for type of information:

REPORTING FORMAT FOR THE ANALOGUE APPROACH

1. HYPOTHESIS FOR THE ANALOGUE APPROACH

For PNEC derivation, all available data for rhodium(III) substances have been pooled and the most sensitive endpoint used as the key value for PNEC derivation. This is a worst-case approach for PNEC derivation and generally follows Scenario 1 of ECHA's Read Across Assessment Framework (ECHA 2017) 'analogue approach: (bio)transformation to common compounds'. The most sensitive result for any rhodium(III) substance is for rhodium trichloride (hydrate), for *Daphnia*. This result is therefore read across from rhodium trichloride (hydrate) (source substance) to diammonium sodium hexakis(nitrito-N)rhodate (target substance) for the purposes of PNEC derivation only, as a worst-case approach. Data are also available for the acute toxicity to *Daphnia* endpoint for diammonium sodium hexakis(nitrito-N)rhodate itself and this is used in preference to read across data for the

purposes of fulfilling the REACH data requirements for diammonium sodium hexakis(nitrito-N)rhodate and for classification of the substance.

However, for PNEC derivation purposes a worst-case approach based on pooled data for all soluble rhodium(III) substances is considered to be appropriate as a single set of PNECs covering all rhodium(III) substances can be derived. As differences in toxicity have been observed for other metals in different oxidation states (e.g. chromium and arsenic) only data for rhodium compounds in the same oxidation state have been considered for PNEC derivation.

2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES)

Source: Rhodium trichloride (hydrate)
Target: Diammonium sodium hexakis(nitrito-N)rhodate
See full Read Across Justification report for discussion on impurities.

3. ANALOGUE APPROACH JUSTIFICATION

The read across hypothesis for PNEC derivation is based on substances containing rhodium in the same oxidation state and a worst case read across approach being used. In the risk assessment, emissions of different rhodium substances are not analysed separately and therefore measured environmental concentrations are available based on total rhodium concentrations. As the measured emissions data is not apportioned to a particular rhodium(III) substance, a single set of PNECs covering all rhodium substances in the same oxidation state is considered to be the most appropriate approach for conducting the risk assessment. Therefore, all data for rhodium(III) substances has been pooled and the PNEC values derived based on the most sensitive result, which is for rhodium trichloride. Available ecotoxocity data for rhodium(III) substances has been assessed to determine if the read across approach is appropriate.

Acute *Daphnia* results are available for diammonium sodium hexakis(nitrito-N)rhodate, rhodium trinitrate (hydrate) and rhodium trichloride (hydrate) and based on the EC50 values there is some indication that rhodium trichloride may be more toxic than the other rhodium substances (diammonium sodium hexakis(nitrito-N)rhodate EC50: 11.8 mg Rh L^{-1}, rhodium trinitrate EC50: 42.8 mg Rh L^{-1}, rhodium trichloride EC50: 0.290 mg Rh L^{-1}). For other precious metals substances, substances with a chloro ligand have been shown to be more toxic in ecotoxicity studies and the same may be true for rhodium substances, however the current dataset is too limited to reach a firm conclusion on this. As rhodium substances with a chloro ligand may be more toxic than those without, it is not recommended that read across between substances with and without chloro ligands is used for completing REACH

data requirements or for classification purposes. However, for the purposes of PNEC derivation a worst-case approach is considered to be appropriate, as if safe use is demonstrated with a PNEC derived based on the result for a substance that is more toxic, this is a precautionary approach. The benefit of deriving one set of PNECs for rhodium(III) substances based on this worst-case data is that all emissions of rhodium(III) substances from a site can be considered in the risk assessment, compared against PNECs expressed on a rhodium basis.

The most sensitive acute test result with diammonium sodium hexakis(nitrito-n)rhodate is the E_rC50 value of 0.66 mg Rh L^{-1} for the alga *Pseudokirchneriella subcapitata*. The invertebrate *Daphnia magna* was notably less sensitive in acute tests with this substance. In tests with rhodium trichloride (hydrate) invertebrates were more sensitive than fish, and the most sensitive acute test result is an EC50 value of 0.290 mg Rh L^{-1} for *Daphnia magna*. The most sensitive acute test result with rhodium trinitrate hydrate is an unbounded E_rC50 of >0.32 mg Rh L^{-1} (E_bC50 = 0.31 mg Rh L^{-1}). Overall there is no clear single most sensitive trophic level for rhodium toxicity, as similar levels of sensitivity have been observed in tests on both algae and invertebrates, albeit with different test substances. However, where both algae and invertebrates have both been tested, algae have been more sensitive, which would suggest that algae could potentially be more sensitive to rhodium trichloride than invertebrates, if a test result for algae were available for this substance. PNECs based on the rhodium trichloride (hydrate) *Daphnia* result could potentially underestimate the toxicity of other rhodium(III) substances with a chloro ligand. However, based on the tonnages of rhodium(III) substances currently manufactured and imported, no rhodium(III) substances containing a chloro ligand are being registered at >10 tpa, and therefore no substances containing a chloro ligand require PNECs to be derived or a risk assessment to be conducted. Using PNECs based on the *Daphnia* result for a rhodium(III) substance containing a chloro ligand to cover rhodium(III) substances without a chloro ligand is therefore still believed to be a conservative approach.

4. DATA MATRIX

See full Read Across Justification report.

Discussion

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

The EC50 was determined to be 81.3 mg L^{-1}.

Additional information:

Acute toxicity to *Daphnia* was assessed according to OECD guideline 202 and EC method C.2

(Simon 2014). The daphnids were placed in water containing the test item in a nominal concentration range of 4.3 to 220 mg L^{-1}, and as measured test concentrations did not deviate by more than 20% of nominal, nominal concentrations were used for reporting of results. The test was conducted under static conditions for 48 h. The study was conducted in accordance with GLP and all validity criteria were met. This study has been given a reliability rating of 1 as it is well-documented and adheres to guideline procedures. No significantly increased mortality was determined up to a concentration of 45.5 mg L^{-1}. The EC50 for the tested species was found to be 81.3 mg test item L^{-1} (95 % CL: 31.8 – 324.3).

For PNEC derivation all data for rhodium(III) substances has been pooled and the PNEC values derived based on the most sensitive result. In the risk assessment, emissions of different rhodium substances are not analysed separately and therefore measured environmental concentrations are available based on total rhodium concentrations. As the measured emissions data is not apportioned to a particular rhodium(III) substance, a single set of PNECs covering all rhodium substances in the same oxidation state is considered to be the most appropriate approach for conducting the risk assessment. For aquatic PNECs the lowest EC50 value is for the rhodium(III) substance rhodium(III) chloride. There is some indication that rhodium substances containing a chloro ligand may be more toxic than those without, and therefore using the value for rhodium trichloride as the key value for PNEC derivation for all rhodium(III) substances is likely to be worst case. The value taken forward for PNEC derivation is therefore a 48-hour EC50 of 0.290 mg Rh L^{-1}, based on a study using rhodium chloride (hydrate).

7.1.2.2. Long-term toxicity to aquatic invertebrates

No relevant information available.

7.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 7.3. Effects on algae and aquatic plants

Method	Results	Remarks
Pseudokirchneriella subcapitata (previous names: *Raphidocelis subcapitata, Selenastrum capricornutum*) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before	EC50 (72h): 4.5 mg/L test mat. (meas. (initial)) based on: growth rate (95% CL 4.23 - 4.78 mg/L) EC50 (72h): 0.522 test mat. (meas. (initial)) based on: Yield (95% CL 0.477 - 0.568 mg/L) EC50 (72h): 0.656 mg/L element (meas. (initial)) based on: growth rate (95% CL 0.616 - 0.696)	1 (reliable without restriction) key study experimental study **Test material** Diammonium sodium hexakis(nitro-N)rhodate

23 March 2006] ; according to EU Method C.3 (Algal Inhibition test)	EC50 (72h): 0.076 mg/L element (meas. (initial)) based on: Yield (95% CL 0.069 - 0.083) NOEC (72h): <0.301 mg/L test mat. (meas. (initial)) based on: growth rate NOEC (72h): <0.301 mg/L test mat. (meas. (initial)) based on: Yield NOEC (72h): <0.044 mg/L element (meas. (initial)) based on: growth rate NOEC (72h): <0.044 mg/L element (meas. (initial)) based on: Yield EC10 (72h): 0.313 mg/L test mat. (meas. (initial)) based on: growth rate (95% CL 0.273 - 0.356 mg/L) EC10 (72h): <0.301 mg/L test mat. (meas. (initial)) based on: Yield EC10 (72h): 0.046 mg/L element (meas. (initial)) based on: growth rate (95% CL 0.040 - 0.052) EC10 (72h): <0.044 mg/L element (meas. (initial)) based on: Yield EC20 (72h): 0.782 test mat. (meas. (initial)) based on: growth rate (95% CL 0.705 - 0.862 mg/L) EC20 (72h): 0.131 mg/L test mat. (meas. (initial)) based on: Yield (95% CL 0.109 - 0.155 mg/L)	**Reference** Wenzel A 2015
Pseudokirchneriella subcapitata (previous names: *Raphidocelis subcapitata, Selenastrum capricornutum*) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]; according to EEC method C.3	EC50 (72h): >14.3 mg/L test mat. (nominal) based on: growth rate EC50 (72h): >2.08 mg/L element (nominal) based on: growth rate NOEC (72h): <2.28 mg/L test mat. (nominal) based on: growth rate NOEC (72h): <0.332 mg/L element (nominal) based on: growth rate EC10 (72h): <2.28 mg/L test mat. (nominal) based on: growth rate EC10 (72h): <0.332 mg/L element	1 (reliable without restriction) key study experimental study **Test material** Diammonium sodium hexakis(nitro-N)rhodate **Reference** Wenzel A 2015

	(nominal) based on: growth rate	

Discussion

Effects on algae / cyanobacteria

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

The 72-hour EC50, EC10 and NOEC were found to be 4.5, 0.313 and < 0.301 mg test item L^{-1}, respectively, for growth rate.

Additional information:

The effect of diammonium sodium hexakis (nitrito-N) rhodate on the growth rate and yield of *Pseudokirchneriella subcapitata* was investigated according to OECD guideline 201 and EEC method C.3 (Wenzel 2015a). Algae were placed in test medium containing the test item at 5 nominal concentrations ranging from 2.00 to 78.3 mg test item L^{-1}, corresponding to nominal rhodium concentrations of 0.219 to 11.4 mg Rh L^{-1}. The test was conducted under static conditions for 72 hours. The test solutions were analysed for rhodium using ICP-OES and test results reported based on measured initial concentrations. Although the concentrations used in the main study were based on the results from a rangefinder study, it was not possible to determine an EC50 or EC10 for growth rate from the study, with results reported as unbounded values. The 72-hour EC50, EC10 and NOEC were found to be >14.3, <2.28 and <2.28 mg test item L^{-1} (>2.08, <0.332 and <0.332 mg Rh L^{-1}), respectively, for growth rate. For yield, the EC50, EC10 and NOEC were all <2.28 mg test item L^{-1} (<0.332 mg Rh L^{-1}).

During the initial test for growth rate, a 50% effect was not achieved and effects appeared to plateau (at around 35-40%) above a nominal concentration of 12.5 mg L^{-1}. However, at the lowest test concentration there was a greater than 10% effect, therefore an EC10 or NOEC could not be derived either. For yield, a greater than 50% effect was observed at all exposure concentrations, therefore no EC50 or EC10 could be derived. As neither an EC50 or EC10 value could be determined from the study, the test was repeated with different test concentrations.

In the repeated test, the effect of diammonium sodium hexakis (nitrito-N) rhodate on the growth rate and yield of *Pseudokirchneriella subcapitata* was investigated according to OECD guideline 201 and EEC method C.3 (Wenzel 2015b). Algae were placed in test medium containing the test item at 7 nominal concentrations ranging from 0.20 to 214.7 mg test item L^{-1}, corresponding to nominal rhodium concentrations of 0.029 to 31.3 mg Rh L^{-1}. The test was conducted under static conditions for 72 hours. The test solutions were analysed for rhodium using ICP-OES and test results reported based on measured initial concentrations.

The 72-hour EC50, EC10 and NOEC were found to be 4.5, 0.313 and < 0.301 mg test item L^{-1} (0.656,

0.046 and <0.044 mg Rh L^{-1}), respectively, for growth rate. For yield, the EC50, EC10 and NOEC were 0.522, <0.301 and <0.301 mg test item L^{-1} (0.076, <0.044 and <0.044 mg Rh L^{-1}), respectively.

7.1.4. Sediment organisms

No relevant information available.

7.1.5. Other aquatic organisms

No relevant information available.

7.2. Terrestrial compartment

7.2.1. Toxicity to soil macro-organisms

No relevant information available.

7.2.2. Toxicity to terrestrial plants

No relevant information available.

7.2.3. Toxicity to soil micro-organisms

No relevant information available.

7.2.4. Toxicity to other terrestrial organisms

No relevant information available.

7.3. Microbiological activity in sewage treatment systems

The results are summarised in the following table:

Table 7.4. Effects on micro-organisms

Method	Results	Remarks
activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to EU Method C.11 (Biodegradation: Activated Sludge Respiration Inhibition Test)	NOEC (3h): >=1000 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate (without ATU) NOEC (3h): >=1000 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate (with ATU) EC50 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate (without	1 (reliable without restriction) key study experimental study **Test material** Diammonium sodium hexakis (Nitrito-N) rhodate(**Reference** Muckle M 2015

	ATU) EC50 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate (with ATU)	

Discussion

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

The NOEC value for both total respiration and heterotrophic respiration was determined to be ≥1000 mg L^{-1}.

Additional information:

This study evaluated the effect of Diammonium sodium hexakis (Nitrito-N) rhodate on the respiration of activated sludge (Muckle 2015). The study is reliable without restrictions, being GLP compliant and having followed the standard guidelines OECD 209, and EU-Method C.11. The duration of the test was 3 hours. Activated sludge, which was collected from a predominantly domestic sewage treatment plant, was used as inoculum. The substance 3,5-dichlorophenol was used as a positive control. Two experiments were carried out, a range-finding test followed by a limit test. All validity criteria were met. At the nominal concentration of 1000 mg L^{-1}, no significant inhibition was observed in treatments with and without the nitrification inhibitor N-allylthiourea (ATU). The respective NOEC value for both total respiration and heterotrophic respiration was determined to be ≥ 1000 mg L-1 nominal concentration.

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

7.4.1. Toxicity to birds

No relevant information available.

7.4.2. Toxicity to mammals

No relevant information available.

7.5. PNEC derivation and other hazard conclusions

Table 7.5. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 0.29 µg/L Intermittent releases:	Assessment factor: 1000 Extrapolation method: assessment factor PNECfreshwater derived based on an EC50 of 0.290

	2.9 µg/L	mg Rh L^{-1}, for *Daphnia*, and an assessment factor of 1000. For further details see attached PNEC report. PNECintermittent releases derived based on an EC50 of 0.290 mg Rh L^{-1}, for *Daphnia* and an assessment factor of 100. For further details see attached PNEC report.
Marine water	PNEC aqua (marine water): 0.029 µg/L Intermittent releases:	Assessment factor: 10000 Extrapolation method: assessment factor PNECmarinewater derived based on an EC50 of 0.290 mg Rh L^{-1}, for *Daphnia* and an assessment factor of 10000. For further details see attached PNEC report.
Sediments (freshwater)	PNEC sediment (freshwater): 4.37 mg/kg sediment dw	Assessment factor: Extrapolation method: equilibrium partitioning method PNECfreshwater sediment derived using equilibrium partitioning based on the aquatic PNEC and a Kd value of 15100 L kg^{-1}. For further details see attached PNEC report.
Sediments (marine water)	PNEC sediment (marine water): 0.44 mg/kg sediment dw	Assessment factor: Extrapolation method: equilibrium partitioning method PNECmarine sediment derived using equilibrium partitioning based on the marine water PNEC and a Kd value of 15100 L kg^{-1}. For further details see attached PNEC report.
Sewage treatment plant	PNEC STP: 14.6 mg/L	Assessment factor: 10 Extrapolation method: assessment factor PNECmicroorganisms derived based on a NOEC of ≥146 mg Rh L^{-1} from a respiration inhibition test and an assessment factor of 10. For further details see attached PNEC report.
Soil	PNEC soil: 0.001 mg/kg soil dw	Assessment factor: Extrapolation method: equilibrium partitioning method PNECsoil derived using equilibrium partitioning based

		on the aquatic PNEC and a Kd value of 3.8 L kg^{-1}. For further details see attached PNEC report.
Air	no hazard identified:	This substance is not expected to contribute to ozone depletion, ozone formation, global warming or acidification. Therefore, the evaluation of atmospheric risk is not required.
Secondary poisoning	no potential to cause toxic effects if accumulated (in higher organisms) via the food chain:	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

Acute *Daphnia* and algae data are available for the substance itself, and acute fish data are read across from rhodium trinitrate (hydrate). The most sensitive trophic level is algae, with an E_rC50 of 4.5 mg test item L^{-1} and an E_rC10 of 0.313 mg L^{-1}. As the EC50 value is above 1 no acute environmental classification is assigned for this substance. As the only chronic data available is an E_rC10 for algae, the chronic classification is determined based on both the acute and chronic data, with the most stringent classification assigned. As this substance is not rapidly degradable, both the acute and chronic data lead to a Chronic Category 2 (H411) classification being assigned to this substance.

General discussion

Tests have been conducted with diammonium sodium hexakis(nitrito-N)rhodate for acute *Daphnia*, algae and toxicity to microorganisms endpoints. As *Daphnia* and algal results are similar for the two substances, and as algae are the most sensitive trophic level and will drive classification, it is considered appropriate to read across data for acute toxicity to fish from another rhodium(III) substance, rhodium trinitrate (hydrate). These data are used for classification purposes.

For PNEC derivation all data for rhodium(III) substances has been pooled and the PNEC values derived based on the most sensitive result. In the risk assessment, emissions of different rhodium substances are not analysed separately and therefore measured environmental concentrations are available based on total rhodium concentrations. As the measured emissions data is not apportioned

to a particular rhodium(III) substance, a single set of PNECs covering all rhodium substances in the same oxidation state is considered to be the most appropriate approach for conducting the risk assessment. For aquatic PNECs the lowest EC50 value is for the rhodium(III) substance rhodium(III) chloride. There is some indication that rhodium substances containing a chloro ligand may be more toxic than those without, and therefore using the value for rhodium trichloride as the key value for PNEC derivation for all rhodium(III) substances is likely to be worst case.

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. PBT/vPvB criteria and justification

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

8.1.2. Summary and overall conclusions on PBT or vPvB properties

PBT assessment

Assessed composition:

Overall conclusion: PBT assessment does not apply.

Justification:

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

8.2. Emission characterisation

Not relevant.

9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.0. Introduction

9.0.1. Overview of uses and Exposure Scenarios

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

Table 1. Overview of exposure scenarios and contributing scenarios

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
ES1 - M1		Manufacture - Manufacture of the substance (as such) - Manufacture of the substance (as such) (ERC 1) - Raw material handling (PROC 8b, 26) - Wet processing (PROC 4) - Separation/Filtration (PROC 4) - Washing/Drying (PROC 4) - Packaging/Filling (PROC 8b) - Cleaning and maintenance (PROC 26)	
ES2 - IW1	PC 19	Use at industrial site - Use as an intermediate - Use as an intermediate (ERC 6a) - Handling of medium/high dusty materials (PROC 26) - Handling of low dusty materials (PROC 26) - Handling of solutions and reaction (PROC 4, 8b) - Vacuum cleaning (PROC 26)	

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)			

9.0.2. Introduction to the assessment

9.0.2.1. Environment

9.0.2.1.1 Regional Background Concentrations

To derive the regional background concentration for environmental compartments EUSES modelling has been undertaken based on regional production volume for the aquatic environment and terrestrial compartment.

For the derivation of the regional background concentrations, the total tonnage of all rhodium (Rh) compounds produced in the EU was sub-divided by region. The value input for the modelling was the maximum proportion of Rh compounds produced in a single region. This regional assumption was combined with emission characteristics from the Rh manufacturing and processing sector data (Tables 1 and 2), STP removal efficiency (Section 9.0.1.1.3) and phys-chem properties to perform calculations of the regional PEC concentrations for freshwater[3] and soil. The estimated regional background PECs were then incorporated into all GESs.

9.0.2.1.2. Local PEC and tiered Risk calculation approach

Assessment has been undertaken of the risks posed to all relevant environmental compartments by releases of Rh during the manufacture and downstream use of diammonium sodium hexakis(nitrito-N)rhodate. Environmental risk assessment has been undertaken based on an extensive and tiered approach to derive Risk Characterisation Ratios (RCR) for all manufacturers and users in all relevant

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

environmental compartments. The assessment initially comprised default EUSES modelling (TIER 1), following by refined modelling and use of metal-specific emission ratios (SPERCs)[4] (TIER 2) and the use of available site-specific emission data (TIER 3). Measured emission data are primarily available from the Rh sector for manufacture of Rh metal and compounds and their subsequent use at the same sites as industrial intermediates. Estimation of environmental concentrations is based on algorithms taken from ECHA technical guidance[3] and risk characterisation is performed by comparison of the 'predicted environmental concentrations' (PECs) against appropriate 'predicted no effect concentrations' (PNECs) derived from ecotoxicological testing of diammonium sodium hexakis(nitrito-N)rhodate and other rhodium (III) compounds.

Tier 1

The environmental modelling of the local PEC was carried out in EUSES by applying default/conservative assumptions. Default exposure scenarios covering the point source emissions to the environment from production and downstream uses of diammonium sodium hexakis(nitrito-N)rhodate were created. Tier 1 local PEC calculations employed default values from the guidance based on the appropriate Environmental Release Category (ERC)[5]. Physico-chemical and fate data discussed in the previous sections of the CSR were used as input values, and the calculated PECs were compared with the PNECs derived in Section 7. If no risks were identified in any compartment or a realistic Msafe tonnage could be calculated, the environmental modelling stopped at this point.

Tier 2

The Tier 1 assessment did not, due to its conservative nature, derive RCR < 1 for most manufacturers or generate representative Msafe tonnage values for downstream user sectors. Prior to the use of site-specific or representative emission data, metal-specific environmental release categories (SpERCs) were applied (http://www.arche-consulting.be/Metal-CSA-toolbox/spercs-tool-for-metals). Again, if no risk was identified or a realistic Msafe tonnage could be calculated, the environmental modelling stopped at this point.

Tier 3

Under Tier 3 assessment, monitoring data from the Rh processing sector were applied where available (i.e. for manufacturers) for emissions to the aquatic environment in conjunction with the use of SpERC release factors (RFs) for emissions to air. The use of site-specific monitoring data to

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

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

generate representative sector emission values for wastewater and SpERC RFs for stack emissions to air resulted in RCR values of <1 for all environmental compartments for the manufacturers who also use Rh compounds as intermediates at the same sites.

9.0.2.1.3 Drafting of ES

For Manufacture and Use as Intermediate at Industrial Sites

Tonnage data were collected from 9 sites and can be considered as representative for the Rh production and processing sector. An overview of the net annual amount of Rh (as metal equivalent) used per site and annual emission days to water and air are given in Table 1.

The median Rh tonnage (50P) used at a single Rh production site on an annual basis is 1.0 tpa, with a 90th percentile (90P) of 4.5 tpa. For the generic exposure scenario (GES) describing manufacture and use as an intermediate a tonnage of 4.5 tpa was selected, representing 90% of the sector tonnage.

Rh is emitted to the environment via the air (primarily via stack emissions) and in wastewater to the aquatic environment. An overview of the emission days per year (d/yr) to water and air is provided in Table 1. This type of information is reported for most of the sites the median number of emission days is 330 d for water and 361 d for air. The lowest of the median values for emission days to water and air (i.e. 330 d/yr) was selected for the GES.

Table 2. Parameter values during manufacture and use as intermediate at industrial sites (ES 1.1, 1.2, 2.1 and 2.2)

Value	Site Tonnage (tpa Rh, 2013-15)	Emission days per site (d/yr)	
		Water	Air
Median (50P)	1.0	330	361
90th % Percentile (90P)	4.5	365	364
Min	0.1	50	360
Max	-	365	365
n	9	8	4
Selected for Exposure Scenario	4.5 (90P)	330 (lowest 50P)	

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

Nine sites across Europe involved in the production and processing of Rh substances submitted local emission and exposure information. These sites produce and process a number of different Rh 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 Rh originating from the production/use of multiple Rh compounds. A sector approach rather than a substance approach is therefore taken to defining the exposure characteristics (i.e. emission and dilution factors) of the environmental GES for Rh compounds (although tonnage values and PNECs are specific to individual Rh substances).

Emissions to water

Wastewater containing Rh compounds is treated in a treatment plant (WWTP) for recovery and to prevent release to the environment. Site specific emission data were collected from the Rh manufacture and processing sector and used to calculate a release factor (RF) for use in the development of a reasonable worst case (RWC) exposure scenario. A median RF applied to the RWC tonnage value (90P) is considered to give a RWC exposure scenario. Aquatic emission data were provided by 6 sites across Europe (see Table 2) that enabled the calculation of a median RF of 0.0113% (i.e. 113 g of Rh is released for each tonne processed, 113 g/T Rh).

It should be noted that the RF derived from sector data is significantly lower than the Kd-adjusted RF that would be recommended for Rh by the SpERC document for the manufacture of metals and metal compounds[5]. Rh has a Kd of 15,100 L/kg which would give an RF of 0.2% (2000 g/T) according to the approach detailed in the SpERC document. Due to the high monetary value of Rh, emissions are minimised as much as possible leading to lower release factors than for other metals (such as those considered for the basis of the SpERCs).

Dilution

The dilution capacity of the receiving water body (and STP where relevant) will considerably influence the PEC values for the aquatic environment. The majority of sites from the Rh manufacturing and processing sector gave information on the flow rates of the ultimate receiving water body, and the STP where relevant. Table 2 provides an overview of the flow rates and dilution capacity for STPs

and receiving water bodies for ES 1: manufacture and ES 2: use as an intermediate at industrial sites. For manufacturing and downstream user scenarios where no dilution factor data were provided, default dilution factors of 10 and 100 for the freshwater and marine environment are applied, with a maximum dilution factor of 1000 applied for freshwater direct discharge exposure scenarios.

Removal of Rh in STPs

For those facilities discharging their wastewater via the sewage system the size of sewage treatment plants (STPs) and their removal efficiency for Rh will also have a significant influence on the PEC in the receiving water body. The removal of Rh in STPs was determined from a sampling programme at three sewage treatment plants (STPs) in Europe; two in Germany, and one in the United Kingdom (UK) were sampled over a 12-month period. All STPs received wastewater from Rh processing sites discharging wastewater that had been treated at on-site wastewater treatment plants (WWTPs). Based on measurements of total Rh in influent and effluent, the median removal efficiency for Rh was calculated to be 48% and this value has been used in exposure modelling as the amount of Rh partitioning to sewage sludge at STPs with the remaining 52% passing through the STP to the receiving water body[6].

Emissions to air

Airborne emissions are treated by in-stack mitigation systems prior to discharge in order to prevent atmospheric emissions and to retain Rh-rich particulates. Only a limited amount of stack emission data were provided, i.e. by only three sites manufacturing and processing Rh metal and compounds. The use of SpERC release factors (RFs) for emissions to air is recommended as a reasonable worst case approach based on the available data (median RF = 22 g/T and average RF = 46 g/T). The appropriate SpERC document is that for ‘manufacture of metal compounds’[7]. The SpERC RF of 0.03% (equivalent to 300 g/T) is used to develop the GES for sites manufacturing Rh compounds.

Table 3: Release factor and dilution capacity for discharge to aquatic environment during manufacture of Rh compounds and their use as intermediates at industrial sites (ES 1.1, 1.2, 2.1 and 2.2)

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

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

Value	Release factor (RF) (g/T)	On-site effluent flow (m^3/d)	STP flow (m^3/d)	River flow rate (m^3/d)	Dilution factor to STP	Dilution factor STP to river
Median (50P)	113	110	35000	1.4×10^7	4173	46
90P	973	1090	566000	1.6×10^7	1.7×10^4	4900
10P	2.0	2.5	2980	9.4×10^5	18	1.8
Min	1.3	2.5	2950	50	17	1.0
Max	1100	2600	1344000	16000000	22818	5300
N	6	8	7	8	7	7
Selected for ES 1.1 & 2.1 Freshwater – via STP	113 (50P)	110 (50P)	3000 (10P STP flow rate)		27 (based on median effluent flow rate & 10P STP flow)	50 (nominal dilution factor based on 50P dilution for sector data)
Selected for ES 1.2 & 2.2 Freshwater – direct discharge to water		3000		1000 max (dilution factor for only site with direct discharge is 4800)		

9.0.2.2. Man via environment

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

9.0.2.3. Workers

Scope and type of assessment

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

Table 4. Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic, long-term	Qualitative	High hazard	Mutagenicity
	Systemic, acute	Not needed	No hazard identified	-
	Local, long-term	Not needed	No hazard identified	-
	Local, acute	Not needed	No hazard identified	-

[8] An assessment of indirect exposure of humans via the environment is generally only conducted if:
• the tonnage >1 000 t/y or
• the tonnage >100 t/Y and the substance is classified as STOT RE 1; or as a carcinogen or mutagen (any category); or as toxic to reproduction (categories 1A or 1B). (ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 3.0, February 2016)

Route	Type of effect	Type of risk characterisation	Hazard conclusion	Most sensitive endpoint
Dermal	Systemic, long-term	Qualitative	High hazard	Mutagenicity
	Systemic, acute	Not needed	No hazard identified	-
	Local, long-term	Not needed	No hazard identified	-
	Local, acute	Not needed	No hazard identified	-
Eye	Local	Not needed	No hazard identified	-

Several soluble rhodium(III) (Rh) substances are known or suspected mutagens, and are classified according to the EU CLP criteria as Muta. 2 (H341; “suspected of causing genetic defects”). In the absence of cancer bioassays (or other data to indicate the potency of any genotoxic or carcinogenic effect), no (semi-)quantitative risk assessment was possible. Consequently, a qualitative methodology has been applied in this risk assessment. However, according to ECHA Guidance on Information Requirements and Chemical Safety Assessment, Part E: Risk Characterisation (ECHA, 2016), numerical exposure estimates have been derived, based on measured data from occupational monitoring. As set out elsewhere in this document, calculated final personal exposure levels in the occupational ES in Section 9 of the CSR incorporate exposure reduction adjustments due to use of respiratory protective equipment (RPE), as relevant for each ES. Requirements for use of RPE, and the associated RPE Assigned Protection Factors (APF), have been based on control of exposure to ensure safe use of the substance at the appropriate hazard banding (i.e. high hazard for diammonium sodium hexakis(nitrito-N)rhodate (‘hexakis-Rh’). Risk characterisation statements made for the various ES are suitably aligned with this approach.

As support for the qualitative risk characterisation of this substance, the derived exposure estimates were also compared to DNELs derived from a repeated-dose oral toxicity study with hexakis-Rh (Török-Bathó, 2015).

As no relevant data on the effects of repeated exposure of laboratory animals to hexakis-Rh by the inhalation or dermal routes (relevant to this occupational assessment) are available, route-to-route extrapolation to calculate DNELs from a reliable combined repeated-dose with reproductive/developmental toxicity screening study by the oral route was considered a suitable alternative (particularly as first pass effects are not expected to be significant for an inorganic compound).

The no-observed-adverse-effect level (NOAEL) for systemic, reproductive and developmental toxicity in a guideline (OECD TG 422) study was the highest tested dose, 1000 mg/kg bw/day, which equates to a dose of 235 mg Rh/kg bw/day. Applying appropriate assessment factors (AFs), as described in Section 5 (above), results in substance-specific DNELs of 47 mg/m^3 by the inhalation route and 133.3 mg/kg bw/day by the dermal route. In terms of elemental rhodium, for comparison to the exposure estimates derived from measured monitoring data, these DNELs are 11 mg Rh/m^3 and 31.3 mg Rh/kg bw/day, respectively.

Comments on assessment approach related to toxicological hazard:

GENERAL GOOD OCCUPATIONAL HYGIENE PRACTICES

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

(i) work clothing is not taken home,

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

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

SPECIFIC MEASURES TO MINIMISE THE RISK FOR MUTAGENICITY

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

TECHNICAL MEASURES

- High level of containment wherever possible.

- Closed systems allow for easy maintenance.
- Wherever possible, all process systems are kept under negative pressure.
- Rhodium substances are handled in dedicated areas.
- Rhodium substances of high dustiness are sometimes handled damp to reduce the potential for dust emissions.

ORGANISATIONAL MEASURES
- All machinery/systems and RMMs are regularly tested for proper functioning.
- Training of workers in use of PPE, equipment and specifically for handling rhodium substances.
- Training of personnel for emergency situations.
- Permits required for non-authorized personnel entering the work area.

QUALITATIVE RISK CHARACTERISATION FOR MUTAGENICITY
The exposure estimates for the individual CES as reported below generally indicate very low exposure levels for the dermal and the inhalation route for rhodium substances, indicating efficient RMMs at the process level. In addition, organisational measures ensure that any residual exposures are controlled. Contamination of adjacent workplaces is excluded by stringent housekeeping measures such as immediate and careful removal of any contamination of surfaces. It is therefore concluded that the risk for mutagenicity is minimised to an extent as technical feasible by the application of all relevant state-of-the-art risk mitigation measures.

QUALITATIVE RISK CHARACTERISATION FOR OTHER EFFECTS
Due to the stringent conditions in place to protect against mutagenicity, any other adverse health effects that can be caused by rhodium substances are inherently prevented.

Please refer to the document "Methodology applied in the occupational exposure scenarios for rhodium 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 (PPE) FOR WORKERS
Use of PPE 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 (ESs) below.
RPE should be selected based on the given APF according to EN 529 and should comply with national legislation. If RPE has to be worn, an APF of 10 represents the required minimum level of protection.
RPE shall only be worn if the following principles are implemented in parallel: The duration of work should take into account the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself and due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore:
(i) be healthy (especially in view of medical problems that may affect the use of RPE), and
(ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair).
The devices recommended in the ES which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and supply of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme

including training of workers.

EYE/FACE PROTECTION

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

9.0.2.4. Consumers

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

9.0.2.5 Physico-chemical properties

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

The substance is classified as Self-heating Category 1 and Oxidising solid Category 3, therefore do not handle until all safety precautions have been read and understood. Taking into consideration the precautionary statements all uses of the substance for all users can be considered safe regarding corrosion to metals.

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

Environment contributing scenario(s):	
Manufacture of the substance (as such)	ERC 1
Worker contributing scenario(s):	
Raw material handling	PROC 8b, 26
Wet processing	PROC 4
Separation/Filtration	PROC 4
Washing/Drying	PROC 4
Packaging/Filling	PROC 8b
Cleaning and maintenance	PROC 26

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

9.1.2.1. Conditions of use

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

9.1.2.2. Releases

The GES and associated risk assessment are concerned with releases of Rh to wastewater and air arising from the manufacture of diammonium sodium hexakis(nitrito-N)rhodate at an industrial site. Wastewater is treated by an on-site wastewater treatment plant (WWTP) prior to discharge to the receiving water body in a number of ways:

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

Airborne emissions are treated by in-stack mitigation systems prior to discharge (all ES). Exposure assessment for the environment is based on representative exposure characteristics from the Rh manufacturing and processing sector for wastewater emissions and SpERC values for stack emissions to air.

A sector-wide monitoring dataset is available, based on emissions of total Rh, resulting from

production and use of a variety of Rh compounds collected during 2013 - 2015 from sites across Europe. In this assessment the release factor (RF) for wastewater is set at 0.0113 % (equivalent to 113 g/T); the 50th percentile measured wastewater release factor from 6 sites. In this assessment the release factor (RF) to air is set at the SpERC RF to air for 'manufacture of metal compounds'[9] of 0.03% (equivalent to 300 g/T).

9.1.2.3. Risk Management Measures (RMMs)

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

9.1.2.4. Exposure Scenario

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for manufacture of diammonium sodium hexakis(nitrito-N)rhodate is detailed below:

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

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

Environmental assessment is based on the estimated emission of diammonium sodium hexakis(nitrito-N)rhodate in wastewater discharge and in stack emissions to air.	
Amounts used	
Annual production/use at a site	ES 1.1 and ES 1.2: 19.2 tonnes diammonium sodium hexakis(nitrito-N)rhodate (4.5 tonnes Rh metal equivalent); 90P from sector data
Frequency and duration of use	
Pattern of release to the environment	330 days per year per site (50P from sector data)
Environment factors not influenced by risk management	
Receiving surface water flow rate	ES 1.1: STP: 3,000 m^3/d (10P STP size from sector data) Receiving water: 147,000 m^3/d (based on 50P dilution factor from sector data) ES 1.2: Receiving water: 2,997,000 m^3/d (maximum allowable dilution factor of 1000; assumption made on knowledge of sector data.)
Dilution capacity, freshwater	ES 1.1: Discharge to freshwater via STP: DF in STP = 27; DF in receiving water = 50 (sector data) ES 1.2: Direct discharge to freshwater: DF = 1,000 (maximum allowable)
Dilution capacity, marine	Not relevent
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: All ES: On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency >99 % (sector data) Release factor after on-site treatment: 113 g/T (50P from sector data) ES 1.1. Off-site municipal sewage treatment plant (STP) Efficiency 48 % (based on European STP monitoring programme[10])	

[10] Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Rhodium Group Metals in Industrial Effluent during Sewage Treatment. In: Abstracts Book of the SETAC

Air: All ES: Treatment of air emissions by wet scrubbers and filters (e.g. fabric, bag, HEPA). Release factor after on-site treatment: 300 g/T (SpERC RF for 'Manufacture of metal compounds'[11])	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	
Municipal Sewage Treatment Plant (STP)	ES 1.1: Yes ES 1.2: No
Discharge rate of the Municipal STP	ES 1.1: 3,000 m^3/d (10P from sector data)
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)
Conditions and measures related to external treatment of waste for disposal	
Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the rhodium content of the waste is elevated enough, internal or external recovery/recycling should be considered. Fraction of daily/annual use expected in waste: 0% Appropriate waste codes: 06 04 05*, 06 05 02*, 10 08 09, 10 08 11, 10 08 16, 10 08 18, 15 02 02*, 16 01 18, 16 08 01, 16 08 06*, 16 08 07*, 19 08 06*, 20 01 40 Suitable disposal: Hazardous waste produced during the manufacture and downstream use is sent to a recycler only marginal amounts are sent to a landfill or an incinerator. Waste containing rhodium is recycled for almost a 100% A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)	
Conditions and measures related to external recovery of waste	
Diammonium sodium hexakis(nitrito-N)rhodate- and other Rh -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility. The sludge from the on-site treatment plant is processed for metal reclamation (recycling).	
3. Exposure and risk estimation	

Europe 26th Annual Meeting – 22-26 May 2016, Nantes, France, Society of Environmental Toxicology and Chemistry

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

Environment [based on total Rh emissions]

ERC 1

ES 1 Production of Diammonium sodium hexakis(nitrito-N)rhodate*

Compartment	Unit	PNEC	$PEC_{regional}$	C_{local}	PEC	RCR	Methods for calculation of environmental concentrations
Discharge to STP (ES 1.1)	mg Rh/L	14.6 mg/L	N.A.	2.7×10^{-4}	2.7×10^{-4}	1.8×10^{-5}	Reasonable worst case exposure modelling based on 90P sector tonnage & 50P release factor
Freshwater via STP (ES 1.1)	mg Rh/L	2.9×10^{-4} mg/L	8.69×10^{-8} mg/L	4.36×10^{-6}	4.44×10^{-6}	0.015	
Freshwater following direct discharge (ES 1.2)	mg Rh/L	2.9×10^{-4} mg/L	8.69×10^{-8} mg/L	4.19×10^{-7}	5.06×10^{-7}	0.00174	
Freshwater sediment via STP (ES 1.1)	mg Rh/kg w.w.	0.95 mg/kg	N.A.[12]	0.00146	0.00146	0.15 ǂ	
Freshwater sediment via direct discharge (ES 1.2)	mg Rh/kg w.w.	0.95 mg/kg	N.A.[10]	0.00166	0.00166	0.0175 ǂ	
Terrestrial (ES 1.1 and 1.2)	mg Rh/kg w.w.	1.00×10^{-3} mg/kg	1.64×10^{-6} mg/kg	2.44×10^{-6} mg/kg	4.08×10^{-6} mg/kg	0.0041	Modelled increase in soil concentrations due to deposition from

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

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

* All concentrations reported as Rh equivalent due to the PNEC based on rhodium concentration being used for assessment.
ǂ Additional factor of 10 applied in RCR calculation to account for use of PNEC derived by equilibrium partitioning.and high degree of partitioning
N.A. = not applicable

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

Environment

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

Scaling of the release to air and water environment includes:

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

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

9.1.3.1. Conditions of use for handling of solid rhodium substances (PROC 8b, 26)

	Method
Product (article) characteristics	
• Physical form of substance: solid rhodium substances	Monitoring data
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported). Lower EPs (e.g. if rhodium substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment. It is further noted that spraying operations of rhodium compounds in liquid/suspension/solution forms are not covered in this assessment.	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate for handling of solid (high dustiness) rhodium substances: - Generic local exhaust ventilation - Exterior exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80% has to be assured.	Monitoring data
• Level of containment: - Rhodium substances are always handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an “incidental or intermittent” contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the rhodium industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data

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

9.1.3.2. Exposure and risks for workers for handling of solid rhodium substances (PROC 8b, 26)

The exposure concentrations (ECs) and risk characterisations (RCs) are reported in the following table.

Table 5. Exposure concentrations and risks for workers (for long-term, systemic effects)

	Rh
RC inhalation route	qualitative
EC inhalation, long-term, systemic	25.5 µg Rh/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.64 µg Rh/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (Rh, WP01)

- Inhalation, systemic, long-term:
  Number of measured data points: 4

  The estimated exposure level used above represents 150% of the maximum measured exposure (17 µg Rh/m³).

Dermal

Analogous data (Ni)

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

Assigned exposure scenario: non-dispersive use, direct handling, incidental exposure (NDI)

The estimated exposure level used above represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves (0.58 µg Ni/cm^2), adjusted as described in more detail in the methodology document.

Conclusion on risk characterisation

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

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

Furthermore, in consideration of the potential other effects besides mutagenicity, comparison of the ECs in Table 3 with the DNELs calculated for this substance from the reliable repeated dose toxicity data (described in Section 9.0.2.3) results in exposure estimates > 1000-fold lower than the DNELs. This provides reassurance that the estimated exposures pose a negligible risk to human health.

9.1.4. Worker contributing scenario 2: Wet processing (PROC 4)

9.1.4.1. Conditions of use for not fully contained wet processes (PROC 4)

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

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

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

9.1.4.2. Exposure and risks for workers for not fully contained wet processes (PROC 4)

The ECs and RCs are reported in the following table.

Table 6. Exposure concentrations and risks for workers (for long-term, systemic effects)

	Rh
RC inhalation route	qualitative
EC inhalation, long-term, systemic	3.28 µg Rh/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.33 µg Rh/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.003 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (Rh, WP03)

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

  The estimated exposure level represents the 95th percentile of the exposure distribution (GSD=1.1).

Dermal

Analogous data (Ni)

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

Assigned exposure scenario: non-dispersive use, non-direct handling, incidental exposure (NNI)

The estimated exposure level used above represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves (0.06 µg Ni/cm^2), adjusted as described in more detail in the methodology document.

Conclusion on risk characterisation

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

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

Furthermore, in consideration of the potential other effects besides mutagenicity, comparison of the ECs in Table 4 with the DNELs calculated for this substance from the reliable repeated dose toxicity data (described in Section 9.0.2.3) results in exposure estimates> 1000-fold lower than the DNELs. This provides reassurance that the estimated exposures pose a negligible risk to human health.

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

9.1.5.1. Conditions of use for handling of rhodium substances (PROC 4)

	Method
Product (article) characteristics	
• Physical form of substance: solid rhodium substances	Monitoring data
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported). Lower EPs (e.g. if rhodium substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment. It is further noted that spraying operations of rhodium compounds in liquid/suspension/solution forms are not covered in this assessment.	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

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

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

9.1.5.2 Exposure and risks for workers for handling of rhodium substances (PROC 4)

The ECs and RCs are reported in the following table.

Table 7. Exposure concentrations and risks for workers (for long-term, systemic effects)

	Rh
RC inhalation route	qualitative
EC inhalation, long-term, systemic	1.5 µg Rh/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.04 µg Rh/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.29 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (Rh, WP04)

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

  The estimated exposure level represents 150% of the maximum measured exposure (1 µg Rh/m³).

Dermal

Analogous data (Ni)

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

Assigned exposure scenario: non-dispersive use, direct handling, extensive exposure (NDE)

The estimated exposure level used above represents the 90th percentile of the exposure distribution for NDE in consideration of appropriate use of gloves (5.18 µg Ni/cm^2), adjusted as described in more detail in the methodology document.

Conclusion on risk characterisation

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

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

Furthermore, in consideration of the potential other effects besides mutagenicity, comparison of the ECs in Table 5 with the DNELs calculated for this substance from the reliable repeated dose toxicity data (described in Section 9.0.2.3) results in exposure estimates > 100-fold lower than the DNELs. This provides reassurance that the estimated exposures pose a negligible risk to human health.

9.1.6. Worker contributing scenario 4: Washing/Drying (PROC 4)

9.1.6.1. Conditions of use for handling of rhodium substances (PROC 4)

	Method
Product (article) characteristics	
• Physical form of substance: solid rhodium substances	Monitoring data
• Maximum emission potential of the substance: Low (Only the highest emission potential (EP) is reported). Lower EPs (e.g. if rhodium substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment. It is further noted that spraying operations of rhodium compounds in liquid/suspension/solution forms are not covered in this assessment.	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data

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

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

9.1.6.2. Exposure and risks for workers for handling of rhodium substances (PROC 4)

The ECs and RCs are reported in the following table.

Table 8. Exposure concentrations and risks for workers (for long-term, systemic effects)

	Rh
RC required for EG, inhalation route	qualitative
EC inhalation, long-term, systemic	3.4 µg Rh/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.09 µg Rh/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC required for EG, dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (Rh, WP05)

- Inhalation, systemic, long-term:
  Number of measured data points: 1

  The estimated exposure level represents 200% of the only measured exposure (1.7 µg Rh/m³).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26
  Assigned exposure scenario: non-dispersive use, direct handling, incidental exposure (NDI)

The estimated exposure level used above represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves (0.58 µg Ni/cm^2), adjusted as described in more detail in the methodology document.

Conclusion on risk characterisation

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

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

Furthermore, in consideration of the potential other effects besides mutagenicity, comparison of the ECs in Table 6 with the DNELs calculated for this substance from the reliable repeated dose toxicity data (described in Section 9.0.2.3) results in exposure estimates > 1000-fold lower than the DNELs. This provides reassurance that the estimated exposures pose a negligible risk to human health

9.1.7. Worker contributing scenario 5: Packaging/Filling (PROC 8b, 26)

9.1.7.1 Conditions of use for handling of solid rhodium substances (PROC 8b, 26)

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

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

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

9.1.7.2. Exposure and risks for workers for handling of solid rhodium substances (PROC 8b, 26)

The ECs and RCs are reported in the following table.

Table 9. Exposure concentrations and risks for workers (for long-term, systemic effects)

	Rh
RC required for EG, inhalation route	qualitative
EC inhalation, long-term, systemic	2.95 µg Rh/m³ (Monitoring data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.07 µg Rh/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC required for EG, dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Monitoring data (Rh, WP09)

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

  The estimated exposure level represents the 95th percentile of the exposure distribution (GSD=1.3).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26
  Assigned exposure scenario: non-dispersive use, direct handling, incidental exposure (NDI)

The estimated exposure level used above represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves (0.58 µg Ni/cm^2), adjusted as described in more detail in the methodology document.

Conclusion on risk characterisation

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

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

Furthermore, in consideration of the potential other effects besides mutagenicity, comparison of the ECs in Table 7 with the DNELs calculated for this substance from the reliable repeated dose toxicity data (described in Section 9.0.2.3) results in exposure estimates > 1000-fold lower than the DNELs. This provides reassurance that the estimated exposures pose a negligible risk to human health.

9.1.8. Worker contributing scenario 6: Cleaning and maintenance (PROC 26)

9.1.8.1. Conditions of use for vacuum cleaning (PROC 26)

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

	Method
• Removal of dusty residuals: A highly efficient vacuum cleaner is to be used. No direct manual removal of dust. Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the rhodium industry. Workplaces are to be cleaned before any maintenance work starts.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Extensive	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier.	
• Eye protection: Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from effects via inhalation exposure (Due to potential mutagenic effects of the substance, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.1.8.2. Exposure and risks for workers for vacuum cleaning (PROC 26)

The ECs and RCs are reported in the following table.

Table 10. Exposure concentrations and risks for workers (for long-term, systemic effects)

	Rh
RC inhalation route	qualitative
EC inhalation, long-term, systemic	25.5 µg Rh/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.64 µg Rh/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.006 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Analogous data (Rh, WP01)

- Inhalation, systemic, long-term:
  Number of measured data points: 4

  The estimated exposure level represents 150% of the maximum measured exposure (17 µg Rh/m³).

Dermal

Analogous data (Ni)

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

Assigned exposure scenario: non-dispersive use, non-direct handling, extensive exposure (NNE)

The estimated exposure level represents the 90th percentile of the exposure distribution for NNE in consideration of appropriate use of gloves (0.11 µg Ni/cm^2), adjusted as described in more detail in the methodology document.

Conclusion on risk characterisation

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

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

Furthermore, in consideration of the potential other effects besides mutagenicity, comparison of the ECs in Table 8 with the DNELs calculated for this substance from the reliable repeated dose toxicity data (described in Section 9.0.2.3) results in exposure estimates > 1000-fold lower than the DNELs. This provides reassurance that the estimated exposures pose a negligible risk to human health .

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

Market sector: Manufacture of other substances

PC 19: Intermediate

Sector of use:

SU 9, Manufacture of fine chemicals

SU 14, Manufacture of basic metals, including alloys

Environment contributing scenario(s):	
Use as an intermediate	ERC 6a
Worker contributing scenario(s):	
Handling of raw materials	PROC 8b, 26
Handling of solutions and reaction	PROC 4, 8b
Vacuum cleaning	PROC 26

Explanation on the approach taken for the ES

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

9.2.1 Environmental contributing scenario 1: Use as an intermediate

9.2.1.1. Conditions of use

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

9.2.1.2 Releases

The GES and associated risk assessment are concerned with releases of Rh to wastewater and air arising from the use of diammonium sodium hexakis(nitrito-N)rhodate as an intermediate at an industrial site. Wastewater is treated by an on-site wastewater treatment plant (WWTP) prior to discharge to the receiving water body in a number of ways:

- To freshwater via a municipal sewage treatment plant (STP) [ES 2.1]; or
- Direct discharge to freshwater [ES 2.2].

Airborne emissions are treated by in-stack mitigation systems prior to discharge (all ES). Exposure assessment for the environment is based on representative exposure characteristics from the Rh manufacturing and processing sector for wastewater emissions and SpERC values for stack emissions to air.

A sector-wide monitoring dataset is available, based on emissions of total Rh, resulting from production and use of a variety of Rh compounds collected during 2013 - 2015 from sites across Europe. In this assessment the release factor (RF) for wastewater is set at 0.0113 % (equivalent to 113 g/T); the 50th percentile measured wastewater release factor from 6 sites. . In this assessment the release factor (RF) to air is set at the SpERC RF to air for 'manufacture of metal compounds'[13] of 0.03% (equivalent to 300 g/T).

9.2.1.3. Risk Management Measures (RMMs)

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

9.2.1.4. Exposure Scenario

The use of diammonium sodium hexakis(nitrito-N)rhodate as an industrial intermediate is considered to have the same operating conditions and emission characteristics as manufacture on the basis that many companies in this sector manufacture diammonium sodium hexakis(nitrito-N)rhodate for use as an intermediate and facilities using this compound as intermediate would be undertaking similar processes.

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for use of diammonium sodium hexakis(nitrito-N)rhodate as an intermediate at industrial sites is detailed below:

1. Title **ES2: Use as an intermediate at industrial site**	
Life cycle	Use as an intermediate at industrial site

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

Systematic title based on use descriRuor	ERC: ERC 6A Use as an intermediate – industrial
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Use as an industrial intermediate
Systematic title based on use descriRuor (environment)	ERC 6A Use as an intermediate – industrial
Processes, tasks, activities covered (environment)	Use as an industrial intermediate: delivery and processing of diammonium sodium hexakis(nitrito-N)rhodate, cleaning & maintenance.
Environmental Assessment Method	Estimates based on monitoring data of emissions, local and regional concentrations are used for calculation of PECs
Product characteristics Diammonium sodium hexakis(nitrito-N)rhodate as solid or aqueous solution. Environmental assessment is based on the estimated emission of diammonium sodium hexakis(nitrito-N)rhodate in wastewater discharge and in stack emissions to air.	
Amounts used	
Annual production/use at a site	ES 2.1 and ES 2.2: 19.2 tonnes diammonium sodium hexakis(nitrito-N)rhodate (4.5 tonnes Rh metal equivalent); 90P from sector data
Frequency and duration of use	
Pattern of release to the environment	330 days per year per site (50P from sector data)
Environment factors not influenced by risk management	
Receiving surface water flow rate	ES 2.1: STP: 3,000 m^3/d (minimum STP size from sector data) Receiving water: 147,000 m^3/d (based on 50P dilution factor from sector data) ES 2.2: Receiving water: 2,997,000 m^3/d (maximum allowable dilution factor of 1000; assumption made on knowledge of sector data.)
Dilution capacity, freshwater	ES 2.1: Discharge to freshwater via STP: DF in STP = 27; DF in receiving water = 50 (sector data) ES 2.2: Direct discharge to freshwater: DF = 1,000 (maximum allowable, based on sector data)
Dilution capacity, marine	Not relevent
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	

Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: All ES: On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99 % (sector data) Release factor after on-site treatment: 113 g/T (50P from sector data) ES 2.1. Off-site municipal sewage treatment plant (STP) Efficiency 48 % (based on European STP monitoring programme[14]) **Air:** All ES: Treatment of air emissions by wet scrubbers and filters (e.g. fabric, bag). Release factor after on-site treatment: 300 g/T (SpERC RF for 'Manufacture of metal compounds'[15])	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	
Municipal Sewage Treatment Plant (STP)	ES 2.1: Yes ES 2.2: No
Discharge rate of the Municipal STP	ES 2.1: 3 000 m^3/d (10P from sector data)
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)
Conditions and measures related to external treatment of waste for disposal	
Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the rhodium content of the waste is elevated enough, internal or external recovery/recycling should be considered. Fraction of daily/annual use expected in waste: 0% Appropriate waste codes: 06 04 05*, 06 05 02*, 10 08 09, 10 08 11, 10 08 16, 10 08 18, 15 02 02*, 16 01 18, 16 08 01, 16 08 06*, 16 08 07*, 19 08 06*, 20 01 40	

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

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

Suitable disposal: Hazardous waste produced during the manufacture and downstream use is sent to a recycler only marginal amounts are sent to a landfill or an incinerator. Waste containing rhodium is recycled for almost a 100%

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)

Conditions and measures related to external recovery of waste

Diammonium sodium hexakis(nitrito-N)rhodate- and other Rh -containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.
The sludge from the on-site treatment plant is processed for metal reclamation (recycling).

3. Exposure and risk estimation

Environment [based on total Rh emissions]
ERC 6A

ES 2 Use as an industrial intermediate*

Compartment	Unit	PNEC	$PEC_{regional}$	C_{local}	PEC	RCR	Methods for calculation of environmental concentrations
Discharge to STP (ES 1.1)	mg Rh/L	14.6 mg/L	N.A.	2.7 $x10^{-4}$	2.7 $x10^{-4}$	1.8 $x10^{-5}$	Reasonable worst case exposure modelling based on 90P sector tonnage & 50P release factor
Freshwater via STP (ES 1.1)	mg Rh/L	2.9 x 10^{-4} mg/L	8.69 $x10^{-8}$ mg/L	4.36 $x10^{-6}$	4.44 $x10^{-6}$	0.015	
Freshwater following direct discharge (ES 1.2)	mg Rh/L	2.9 x 10^{-4} mg/L	8.69 $x10^{-8}$ mg/L	4.19 $x10^{-7}$	5.06 $x10^{-7}$	0.0017 4	
Freshwater sediment via STP	mg Rh/kg	0.95 mg/kg	N.A.[16]	0.001 46	0.00146	0.15 ǂ	

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

(ES 1.1)	w.w.						
Freshwater sediment via direct discharge (ES 1.2)	mg Rh/kg w.w.	0.95 mg/kg	N.A.[14]	0.00166	0.00166	0.0175 [ł]	
Terrestrial (ES 1.1 and 1.2)	mg Rh/kg w.w.	1.00 x 10^{-3} mg/kg	1.64 x10^{-6} mg/kg	2.44 x10^{-6} mg/kg	4.08 x10^{-6} mg/kg	0.0041	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)

* All concentrations reported as Rh equivalent due to the PNEC based on rhodium concentration being used for assessment.

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

N.A. = not applicable

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

Environment

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

Scaling of the release to air and water environment includes:

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

9.2.2. Worker contributing scenario 1: Handling of medium/high dusty materials

(PROC 8b, 26)

9.2.2.1. Conditions of use (PROC 26)

	Method
Product (article) characteristics	
• Physical form of substance: solid	Analogous data
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported). Lower EPs (e.g. if rhodium substances of lower dustiness are being handled in parallel) are thus automatically covered in this assessment. It is further noted that spraying operations of rhodium compounds in liquid/suspension/solution forms are not covered in this assessment.	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate: - Generic local exhaust ventilation - Exterior exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80% has to be assured.	Analogous data
• Level of containment: - Rhodium substances have to be handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	

	Method
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the rhodium industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Direct handling - Contact level: Intermittent	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier.	
• Eye protection: Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from effects via inhalation exposure (Due to potential mutagenic effects of the substance, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.2.2. Exposure and risks for workers

The ECs and RCs are reported in the following table.

Table 11. Exposure concentrations and risks for workers (for long-term, systemic effects)

	Rh
RC inhalation route	qualitative
EC inhalation, long-term, systemic	25.5 µg Rh/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.64 µg Rh/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.03 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Analogous data (Rh, manufacturer WP01)

- Inhalation, systemic, long-term:
  Number of measured data points: 4

  The represents 150% of the maximum measured exposure (17 µg Rh/m³).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 26
  Assigned exposure scenario: non-dispersive use, direct handling, incidental exposure (NDI)

  The estimated exposure level used above represents the 90th percentile of the exposure distribution for NDI in consideration of appropriate use of gloves (0.58 µg Ni/cm^2), adjusted as described in more detail in the methodology document.

Conclusion on risk characterisation

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

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

Furthermore, in consideration of the potential other effects besides mutagenicity, comparison of the ECs in Table 9 with the DNELs calculated for this substance from the reliable repeated dose toxicity data (described in Section 9.0.2.3) results in exposure estimates > 1000-fold lower than the DNELs. This provides reassurance that the estimated exposures pose a negligible risk to human health.

9.2.3. Worker contributing scenario 2: Handling of solutions and reaction (PROC 4, 8b)

9.2.3.1. Conditions of use (PROC 4, 8b)

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

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• The following types of exhaust ventilations are appropriate: - Generic local exhaust ventilation - Integrated exhaust ventilation A minimum efficiency of 80% has to be assured.	Analogous data
• Level of containment: - Rhodium substances have to be handled in at least partly-contained systems with only limited manual interventions. - The level of containment should be as high as possible, easy maintenance should be allowed by system design.	
• Level of automation: The level of automation should be as high as possible in order to reduce potential for exposure. This is inherently covered in the dermal exposure assessment by the reflection of an "incidental or intermittent" contact level (please refer to the dermal exposure pattern below).	
• Removal of residuals: Splashes are to be removed immediately, before drying. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the rhodium industry.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Intermittent	Analogous data

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

9.2.3.2. Exposure and risks for workers

The ECs and RCs are reported in the following table.

Table 22. Exposure concentrations and risks for workers (for long-term, systemic effects)

	Rh
RC inhalation route	qualitative
EC inhalation, long-term, systemic	3.28 µg Rh/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 10: 0.33 µg Rh/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.003 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Analogous data (Rh, manufacturer WP03)

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

  The estimated exposure level represents the 95th percentile of the exposure distribution (GSD=1.1).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7
  Assigned exposure scenario: non-dispersive use, non-direct handling, incidental exposure (NNI)

  The estimated exposure level used above represents the 90th percentile of the exposure distribution for NNI in consideration of appropriate use of gloves (0.06 µg Ni/cm^2), adjusted as described in more detail in the methodology document.

Conclusion on risk characterisation

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

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

Furthermore, in consideration of the potential other effects besides mutagenicity, comparison of the ECs in Table 10 with the DNELs calculated for this substance from the reliable repeated dose toxicity data (described in Section 9.0.2.3) results in exposure estimates > 1000-fold lower than the DNELs. This provides reassurance that the estimated exposures pose a negligible risk to human health.

9.2.4. Worker contributing scenario 3: Vacuum cleaning (PROC 26)

9.2.4.1. Conditions of use for vacuum cleaning (PROC 26)

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

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• Removal of dusty residuals: A highly efficient vacuum cleaner is to be used. No direct manual removal of dust. Removal of dusty residuals is considered to be part of regular work. Dust may not be blown off with compressed air. Please refer to the introduction for more detailed information on how clean work environments are ensured and on how to contamination is avoided in the rhodium industry. Workplaces are to be cleaned before any maintenance work starts.	
• Dermal exposure pattern: - Pattern of use: Non-dispersive use - Pattern of exposure control: Non-direct handling - Contact level: Extensive	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier.	
• Eye protection: Suitable eye protection equipment (e.g. goggles or visors) must be worn.	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from effects via inhalation exposure (Due to potential mutagenic effects of the substance, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.) Please note that higher APFs may be required as reported in exposure and risk section for this sub-contributing exposure scenario.	

9.2.4.2. Exposure and risks for workers for vacuum cleaning (PROC 26)

The ECs and RCs are reported in the following table.

Table 33. Exposure concentrations and risks for workers

	Rh
RC inhalation route	qualitative
EC inhalation, long-term, systemic	25.5 µg Rh/m³ (Analogous data)
EC inhalation, long-term, systemic in consideration of APF	APF = 40: 0.64 µg Rh/m³
RC inhalation, long-term, systemic	risk adequately controlled
RC dermal route	qualitative
EC dermal, long-term, systemic	0.006 mg/kg bw/day (Analogous data)
RC dermal, long-term, systemic	risk adequately controlled
RC combined long-term, systemic	risk adequately controlled

EC = Exposure concentration; RC = Risk characterisation

Remarks on exposure data

Inhalation

Analogous data (Rh, manufacturers WP01)

- Inhalation, systemic, long-term:
  Number of measured data points: 4

  The estimated exposure level represents 150% of the maximum measured exposure (17 µg Rh/m³).

Dermal

Analogous data (Ni)

- Dermal, systemic, long-term:
  Number of measured data points: 7
  Assigned exposure scenario: non-dispersive use, non-direct handling, extensive exposure (NNE)

  The estimated exposure level represents the 90th percentile of the exposure distribution for NNE in consideration of appropriate use of gloves (0.11 µg Ni/cm^2), adjusted as described in more detail in the methodology document.

Conclusion on risk characterisation

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

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

Furthermore, in consideration of the potential other effects besides mutagenicity, comparison of the ECs in Table 11 with the DNELs calculated for this substance from the reliable repeated dose toxicity data (described in Section 9.0.2.3) results in exposure estimates > 1000-fold lower than the DNELs. This provides reassurance that the estimated exposures pose a negligible risk to human health.

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 rhodium substances handled in parallel at the same workplace,
2. More than just a single contributing occupational exposure scenario relevant for an individual worker,
3. Workers that are also exposed to rhodium substances in their free time are not considered relevant as soluble rhodium substances are not available for consumers.

These scenarios are considered below:

1. Multiple rhodium substances handled in parallel at the same workplace

Exposure monitoring data were obtained from a number of workplaces where rhodium and/or rhodium substances are manufactured or used in parallel. Any samples are analysed for their total soluble rhodium content rather than for the content of the respective rhodium substance. Thus, measured rhodium levels are intrinsically reflective of any potential parallel exposure to multiple rhodium substances and are not only relevant for a single rhodium substance. An exposure assessment based on such monitoring data can therefore be considered to include an assessment for any rhodium substance handled in parallel.

2. More than just a single contributing occupational exposure scenario relevant for an individual worker

For aggregated exposure resulting from the applicability of more than just a single contributing worker scenario in a single work shift, it is noted that all exposure levels were derived for a full-shift exposure time and a safe use was demonstrated for each contributing scenario. Thus, by demonstrating safe use for individual contributing scenarios it is assured that a combination of activities within a single shift, could not lead to any adverse effect.

10.1.2. Consumer

Not relevant.

10.2. Environment (combined for all emission sources)

All exposure scenarios detailed in this document include estimates of background concentrations of total rhodium in water, sediment and soil (calculated using the EUSES model and the maximum proportion of the continental tonnage being manufactured and used in one region). The ES for manufacturing and industrial intermediate use is based on a sector-wide approach based on monitoring data for total rhodium and considering ALL forms of rhodium processed at these sites. Additionally, each member company of the PMRC processing rhodium compounds has a site-specific risk assessment based on the manufacture and use of all rhodium compounds at their site; each of these assessments demonstrates an acceptable level of risk. and they are available from each member company on request.

Annexes

1. Annex: References

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