CHEMICAL SAFETY REPORT

Substance Name: Tetraammonium decachloro-mu-oxodiruthenate(4-)

EC Number: 286-924-7

CAS Number: 85392-65-0

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 Tetraammonium decachloro-mu-oxodiruthenate(4-) is a mono-constituent substance (inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

Table 1.1. Substance identity

EC number:	286-924-7
EC name:	Tetraammonium decachloro-µ-oxodiruthenate(4-)
CAS number (EC inventory):	85392-65-0
CAS number:	85392-65-0
IUPAC name:	Tetraammonium decachloro-mu-oxodiruthenate(4-)
Molecular formula:	Cl10ORu2.4H4N

1.2. Composition of the substance

Overall information on composition

Composition	Related composition(s)
Tetraammonium decachloro-mu-oxodiruthenate(4-) (boundary composition of the substance)	

Name: Tetraammonium decachloro-mu-oxodiruthenate(4-) (Boundary composition)

State/form: solid: particulate/powder

Degree of purity: >=84 - <=100 % (w/w)

Description: Mono-constituent substance

Table 1.4. Constituents (Tetraammonium decachloro-mu-oxodiruthenate(4-))

Constituent	Typical concentration	Concentration range	Remarks
Tetraammonium decachloro-mu-oxodiruthenate(4-) EC no.: 286-924-7	98 % (w/w)	>=84 - <=100 % (w/w)	

Table 1.5. Impurities (Tetraammonium decachloro-mu-oxodiruthenate(4-))

Constituent	Typical concentration	Concentration range	Remarks
water EC no.: 231-791-2	<1 % (w/w)	>=0 - <=5 % (w/w)	
Diammonium pentachloro nitrosylruthenate EC no.: 237-504-7	<1 % (w/w)	>=0 - <=10 % (w/w)	
ammonium chloride EC no.: 235-186-4	0.7 % (w/w)	>=0 - <=6 % (w/w)	
Impurities EC no.:	0.3 % (w/w)	>=0 - <=0.5 % (w/w)	Several minor (especially metallic, e.g. Ag, Au, Cu, Ir, Pd, Pt, Rh) impurities which do not affect the classification of the substance because of their non-hazardous nature or because they do not exceed the classification cut-off limits in the substance

1.3. Physicochemical properties

Table 1.6. Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state	Tetraammonium decachloro-mu-oxodiruthenate(4-) is a black powder.	**Value used for CSA:** solid at 20°C and 101.3 kPa The appearance of the test item is

		taken from the test material section of a GLP-compliant report on the physico-chemical properties of the material (Tremain and Atwal 2011). Tetraammonium decachloro-mu-oxodiruthenate(4-) is a black powder. Based on information from the registrants the substance can be black to dark purple / maroon in colour.
Melting / freezing point	Tetraammonium decachloro-mu-oxodiruthenate (4-) decomposed from approximately 340°C, with no definitive signs of melting below 450°C.	**Value used for CSA:** Tremain and Atwal (2011) is a GLP compliant study following OECD guideline 102 and EU method A1 and is considered suitable for use as the key study for this endpoint. Tetraammonium decachloro-mu-oxodiruthenate (4-) decomposed from approximately 340°C, with no definitive signs of melting below 450°C.
Relative density	The density of tetraammonium decachloro-mu-oxodiruthenate(4-) is 2.19 - 2.23 g/cm^3 at 25°C, over 3 runs.	**Value used for CSA:** 2.23 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. In the density test, the substance was identified as ammonium hexachlororuthenate in the test report. The substance identity is equivalent to tetraammonium decachloro-mu-oxodiruthenate(4-). The density of tetraammonium decachloro-mu-oxodiruthenate(4-) is 2.19 - 2.23 g/cm^3 at 25°C, over 3 runs.
Granulometry	The proportion of tetraammonium decachloro-mu-oxodiruthenate (4-) <100 µm was 0 %.	Tremain and Atwal (2011) is a GLP compliant study following OECD guideline 110 (screening test) and is

		considered suitable for use as the key study for this endpoint. The proportion of tetraammonium decachloro-mu-oxodiruthenate (4-) < 100 µm was 0%. In the dustiness test, the substance was identified as diammonium hexachlororuthenate in the test report. The substance identity is equivalent to tetraammonium decachloro-mu-oxodiruthenate(4-). The substance was tested in a modified Heubach procedure according to the guideline DIN 55992-1:2006 (Selck and Parr 2011). The study is non-GLP, but follows a standard guideline and is considered to be reliable. The total dustiness of the test item was determined to be 341.30 mg/g. The inhalable fraction was 207.74 mg/g, the thoracic fraction was 46.94 mg/g and the respirable fraction was 8.61 mg/ g. The Mass Median Aerodynamic Diameter (MMAD) was 28.96 µm with Geometric Standard Deviation of 2.21 µm.
Water solubility	The water solubility of tetraammonium decachloro-mu-oxodiruthenate was reported as 31.1 g/L at 20°C.	**Value used for CSA:** 31.1 g/L at 20°C Gregory (2014) followed a standard shake flask method and is reported in a published article. The water solubility of tetraammonium decachloro-mu-oxodiruthenate was reported as 31.1 g/L at 20°C.
Autoflammability / self-ignition temperature	Tetraammonium decachloro-mu-oxodiruthenate(4-) showed no signs of self-heating when held at 140 °C for 24 hours. When heated between 140 to	**Value used for CSA:** 388°C at 1013 hPa Tremain and Atwal (2011) is a GLP compliant study following a modified

	400 °C, self-heating occurred at 388 °C.	UN N4 method and is suitable for use as the key study for this endpoint. Tetraammonium decachloro-mu-oxodiruthenate(4-) showed no signs of self-heating when held at 140 °C for 24 hours. When heated between 140 to 400 °C, self-heating occurred at 388 °C.
Flammability	Tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.	**Value used for CSA:** not classified Tremain and Atwal is a GLP compliant study following UN method N1 and is considered suitable for use as the key study for this endpoint. Tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.
Oxidising properties	Tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as an oxidising solid in accordance with CLP regulations.	**Value used for CSA:** non oxidising Tremain and Atwal (2011) is a GLP compliant study following UN method O.1 and is considered suitable for use as they key study for this endpoint. Tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as an oxidising solid 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: the study does not need to be conducted because the melting point is above 300°C [study scientifically not necessary / other information available]

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

Reason: study 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]

Information requirement: Explosive properties

Reason: study scientifically not necessary / other information available

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

Discussion of physicochemical properties

Additional information:

Physico-chemical endpoints are completed for this substance based on test data, data from reliable peer-reviewed handbooks and appropriate data waivers.

Based on the available study results and the structure of the substance it is not classified for physico-chemical endpoints.

2. MANUFACTURE AND USES

2.1. Manufacture

Table 2.1. Manufacture

	Manufacture
M-1	**Manufacture (of the substance as such)** Further description of manufacturing process: Tetraammonium decachloro mu-oxodiruthenate is produced by precipitation from ruthenium chloride solution after addition of ammonium chloride. Contributing activity/technique for the environment : **- (ERC1)** Contributing activity/technique for the workers : **- (PROC 1)** **- (PROC 3)** **- (PROC 4)** **- (PROC 8a)** **- (PROC 8b)** **- (PROC 9)** **- (PROC 26)**

2.2. Identified uses

Table 2.2. Uses at industrial sites

	Uses at industrial sites
IW-1	**Use as an intermediate** Further description of the use: Contributing activity/technique for the environment : **- (ERC6a)** Contributing activity/technique for the workers : **- (PROC 3)** **- (PROC 4)** **- (PROC 8a)** **- (PROC 8b)** **- (PROC 9)**

	- (PROC 22) - (PROC 23) - (PROC 26) **Sector of end use:** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) ; SU 9: Manufacture of fine chemicals ; SU 14: Manufacture of basic metals, including alloys ; SU 24: Scientific research and development **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: Tetraammonium decachloro-mu-oxodiruthenate(4-)

Implementation: EU

Related composition: Boundary Composition

The substance is classified as follows:

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

Hazard class	Hazard category	Hazard statement	Reason for no classification
Explosives:			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:			conclusive but not sufficient for classification

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:			conclusive but not sufficient for classification
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:	Eye Damage 1	H318: Causes serious eye damage.	
Respiratory sensitisation:			data lacking
Skin sensitisation:	Skin Sens. 1B	H317: May cause an allergic skin reaction.	
Aspiration hazard:			data lacking
Reproductive Toxicity:			conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:			conclusive but not sufficient for

			classification
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 environmental hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):	Aquatic Acute 1	H400: Very toxic to aquatic life.	
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects.	
M-Factor acute: 1			
M-Factor chronic: 1			
Hazardous to the ozone layer:			data lacking

Labelling

Signal word: Danger

Hazard pictogram:

Figure 3.1.

GHS05: corrosion

Figure 3.2.

GHS07: exclamation mark

Figure 3.3.

GHS09: environment

Hazard statements:

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H400: Very toxic to aquatic life.

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

Precautionary statements:

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

P102: Keep out of reach of children.

P103: Read label before use.

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/…

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

P310: Immediately call a POISON CENTER/doctor/…

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

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

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

P391: Collect spillage.

P501: Dispose of contents/container to ... …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:

Additional information:

A review of information on the partitioning of radioisotopes of several metals (Ciffroy et al. 2009), including ruthenium, summarised information from several other studies of ruthenium partitioning to suspended particulate matter or sediment. This study derived a probability density function for the partition coefficient of ruthenium ranging from a 5th percentile of 10000 L kg^{-1} to a 95th percentile of 100000 L kg^{-1}, with a mode of 31600 L kg^{-1} (modal logKd 4.5, 5th %ile 4.0, 95th %ile 5.0). The studies included in this review were subject to a detailed review, with the intention of deriving conditional partition coefficients for different types of water conditions, although there were insufficient data to enable this approach to be taken for ruthenium. The partition coefficient derived for ruthenium was based on a total of 74 data points, from three studies, covering five different environmental systems.

The Kd for soil was determined to be 6320 L kg^{-1} (log Kd 3.8) based on the modal log Kd from Ciffroy et al. (2009), converted based on a standard soil with 2 % organic carbon.

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: other justification

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: study technically not feasible

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

4.1.2.1.2. Simulation tests (water and sediments)

No relevant information available.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

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 Partition coefficient derived based on 74 data points from 3 studies no guideline required A probability density function was derived for ruthenium based on data collated from several publications. For ruthenium, 74 data points were included taken from 3 studies covering 5 environmental systems. The aim of the study was to derive conditional probability density functions, based on different environmental conditions. However, due to the scarcity of data for ruthenium, only a non-conditional probability density function was built.	Adsorption coefficient: log Kd: 4.5 dimensionless (Modal Kd based on 74 data points from 3 studies) log Kd: 4 dimensionless (5th percentile based on 74 data points from 3 studies) log Kd: 5 dimensionless (95th percentile based on 74 data points from 3 studies)	2 (reliable with restrictions) key study calculation (if not (Q)SAR) - Kd value determined based on a probability density function derived using a dataset of 74 data points from 3 studies **Test material** Ruthenium, **Reference** Ciffroy P., Durrieu G., Garnier J-M. 2009
adsorption / desorption: screening	Adsorption coefficient: log Kd: 4.5 dimensionless (Modal Kd based on 74 data points from 3 studies) log Kd: 4 dimensionless (5th percentile based on 74 data points from 3 studies) log Kd: 5 dimensionless (95th percentile based on 74 data points from 3 studies)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) - Kd value determined based on a

		probability density function derived using a dataset of 74 data points from 3 studies (justification available in appendix 2) **Test material** Ruthenium, **Reference** Ciffroy P., Durrieu G., Garnier J-M. 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 ruthenium substances is conducted based on total emissions of ruthenium. This is a worst-case approach as emissions of all ruthenium substances are combined and taken into consideration when determining the Predicted Environmental Concentration of ruthenium, that is used in the risk assessment. As the exposure aspect of the risk assessment is conducted to cover all ruthenium substances, a single Kd value for ruthenium is used to model the partitioning of ruthenium once released to the environment. The actual form of ruthenium that is present in the environment following release of different ruthenium substances is unknown and using different Kd values for each ruthenium substance is not practical or necessarily relevant for risk assessment. One set of Kd values for ruthenium are therefore considered more appropriate for use in risk assessment.

2. SOURCE AND TARGET CHEMICAL(S)

Source chemical: Ruthenium
Target chemical: Tetraammonium decachloro-mu-oxodiruthenate(4-)

3. ANALOGUE APPROACH JUSTIFICATION

For risk assessment purposes, total measured ruthenium concentrations in the environment are used in order to assess environmental exposure. The exposure assessment conducted does not differentiate between ruthenium substances but covers all emissions of ruthenium substances from a site. As ruthenium emissions are assessed together, Kd values for ruthenium and not for individual ruthenium substances are relevant.

Discussion

The following information is taken into account for any environmental exposure assessment:
For ruthenium, the log Kd for suspended matter is 4.5 (Kd 31600 L kg-1). The log Kd for soil is 3.8 (Kd 6320 L kg-1).

Value used for CSA:
Other adsorption coefficients:

log Kp (solids-water in suspended matter): 4.5 at 20°C

log Kp (solids-water in soil): 3.8 at 20°C

log Kp (solids-water in sediment): 4.5 at 20°C

Additional information:
A review of information on the partitioning of radioisotopes of several metals (Ciffroy et al. 2009), including ruthenium, summarised information from several other studies of ruthenium partitioning to suspended particulate matter or sediment. This study derived a probability density function for the partition coefficient of ruthenium ranging from a 5th percentile of 10000 L kg^{-1} to a 95th percentile of 100000 L kg^{-1}, with a mode of 31600 L kg^{-1} (modal logKd 4.5, 5th %ile 4.0, 95th %ile 5.0). The studies included in this review were subject to a detailed review, with the intention of deriving conditional partition coefficients for different types of water conditions, although there were insufficient data to enable this approach to be taken for ruthenium. The partition coefficient derived for ruthenium was based on a total of 74 data points, from three studies, covering five different environmental systems. The Kd for soil was determined to be 6320 L kg^{-1} (log Kd 3.8) based on the modal log Kd from Ciffroy et al. (2009), converted based on a standard soil with 2 % organic carbon.

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

Additional information:

For ruthenium, the log Kd for suspended matter is 4.5 (Kd 31600 L kg^{-1}). The log Kd for soil is 3.8 (Kd 6320 L kg^{-1}).

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 7.5 “PNEC derivation and other hazard conclusions”).

5. HUMAN HEALTH HAZARD ASSESSMENT

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

5.1.1. Non-human information

No relevant information available.

5.1.2. Human information

No relevant information available.

5.1.3. Summary and discussion of toxicokinetics

The following information is taken into account for any hazard / risk assessment:
Tetraammonium decachloro-μ-oxodiruthenate(4-) (tetradoRu) is likely to be poorly absorbed after oral exposure, with rapid excretion of any material that is absorbed. As such, an oral absorption value of 1% is proposed for chemical safety assessment (CSA) and DNEL derivation.

Although exposure by the inhalation route is anticipated to be low, inhalation absorption is potentially extensive. In line with ECHA guidance, and in the absence of any experimental data to the contrary, a conservative value of 100% inhalation absorption is proposed for CSA and DNEL derivation.

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

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 (%): 1
Absorption rate - dermal (%): 10
Absorption rate - inhalation (%): 100

Additional information:

Absorption

The dataset for toxicokinetics of ruthenium and its salts is very limited, with most studies investigating the simple salt ruthenium (III) chloride (RuCl3) hydrate. In a series of studies, covering oral, intraperitoneal and intravenous administration to rodents, dogs and primates, the toxicokinetic profile of RuCl3 was found to be fairly consistent between the species. Oral absorption was low (up to around 3%) (Furchner et al., 1971).

In another study, radiolabelled 103RuCl3 was administered to a single, healthy male volunteer by contamination of edible clams. About 3 µCi of radiation was administered, and the distribution of the tracer was followed by a whole body scanner for 58 days. Only 1% of the administered dose was considered to be absorbed, with a half-life of 30 days. Absorption of chloro-nitrosyl ruthenium (III) complexes was found to be approximately 3-times that of simple chlorinated ruthenium (III) or (IV) complexes (Yamagata et al., 1969).

On the basis of the above studies, a figure of 1% oral absorption is proposed to be taken forward for chemical safety assessment (CSA).

No good-quality data were found regarding absorption of ruthenium compounds following inhalation. Particle size distribution (PSD) data, as measured by simple sieving, indicate that none of the Tetraammonium decachloro-µ-oxodiruthenate(4-)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 (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, 0.18 and 0.26% 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. As a water soluble substance (20-30 g/L; Gregory, 2012; 2014), any Tetraammonium decachloro-µ-oxodiruthenate(4-)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 unlikely that Tetraammonium decachloro-µ-oxodiruthenate(4-)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 for chemical safety assessment.

No substance-specific data on dermal uptake of Tetraammonium decachloro-µ-oxodiruthenate(4-)were identified. The “high” water solubility (> 10 g/L) suggests that the substance may be too hydrophilic to cross the lipid-rich environment of the stratum corneum to a significant extent, indicating

that a low default value for dermal absorption is appropriate in this case; 10% is the lower of the two values provided by the guidance (ECHA, 2014). However, in vitro permeation studies on soluble platinum and rhodium salts, generally showed a lower degree of absorption [around 1%] than this default would assume. It is reasonable to expect ruthenium and its salts to behave similarly.

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). There is evidence that Tetraammonium decachloro-µ-oxodiruthenate(4-)does not cause skin irritation (Hargitai, 2015), which could facilitate a greater degree of dermal uptake.

Overall, and in the absence of experimental data to the contrary, it is considered suitably health precautionary to take forward the lower of the two ECHA default values for dermal absorption, of 10% for use in CSA and DNEL derivation.

Distribution/Metabolism
Once absorbed, distribution of Tetraammonium decachloro-µ-oxodiruthenate(4-)throughout the body is expected based on a relatively low molecular weight (≈350 g/mol).

As no adverse toxicological effects were reported in a combined repeated dose and reproductive/developmental toxicity dietary study in rats on Tetraammonium decachloro-µ-oxodiruthenate(4-) (Hansen, 2017), no insights can be gained regarding potential tissue distribution/target organs.

Elimination (and Bioaccumulation)
Following oral administration of radiolabelled soluble 106Ru (as 106RuCl3) to mice, rats, monkeys and dogs, > 95% of the administered dose was excreted in the faeces within 3 days. The remainder (1 – 5%) was excreted in the urine, with only trace amounts of ruthenium being retained. The urine and faeces were also the primary routes of elimination following intravenous injection of monkeys or dogs, and intraperitoneal injection of mice and rats. Elimination was much slower following injection administration of 106RuCl3, with only 20-30% of the administered dose detected in the urine, and 4 – 19% in the faeces, after 3 days (Furchner et al., 1971).

In a single human volunteer, given 103RuCl3 in food, similar results were obtained. About 95% of the administered dose was detected excreted in the faeces within 2 days. Approximately 4% was retained in the GI tract, but not considered to be absorbed. The biological half-life of this fraction was 2.3 days (Yamagata et al., 1969).

It is noted that certain metals and ions (notably lead) may interact with the matrix of the bone, causing

them to accumulate within the body (ECHA, 2014). Tetraammonium decachloro-µ-oxodiruthenate(4-)is considered to have only a low potential for bioaccumulation based on its predicted physico-chemical properties (especially a high water solubility of 20-30 g/L).

Conclusion
Based on limited experimental data on another soluble ruthenium salt, as well as substance-specific physico-chemical properties, chemical structure and molecular weight, tetraammonium decachloro-µ-oxodiruthenate(4-) (tetradoRu) is likely to be poorly absorbed after oral exposure. Bioaccumulation is unlikely, and Tetraammonium decachloro-µ-oxodiruthenate(4-)is expected to be rapidly excreted if 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 1%, 10% and 100% for the oral, dermal and inhalation routes, respectively, are proposed for the CSA, and 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] (CD / Crl:CD(SD)) female oral: gavage according to OECD Guideline 425 (Acute Oral Toxicity: Up-and-Down Procedure)	LD50: 3110 mg/kg bw (female) based on: (test mat.)	1 (reliable without restriction) key study experimental study **Test material** 85392-65-0 / 286-924-7; Tetraammonium-decachloro-µ-oxoruthenate (IV), Form: solid: particulate/powder - migrated information: powder **Reference**

		Haferkorn 2016

5.2.1.2. Acute toxicity: inhalation

No relevant information available.

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: other justification

Justification: See ‘Remark’ - In accordance with Column 2 of REACH Annex VIII, this study does not need to be conducted as human exposure via inhalation of aerosols, particles or droplets of an inhalable size is unlikely. Particle size distribution (PSD) data, as measured by simple sieving, indicate that 0% of tetraammonium decachloro-mu-oxodiruthenate is <100 µm (Tremain and Atwal, 2011). Dustiness testing, a more energetic PSD measurement, with the compound (substance identity previously referred to as diammonium hexachlororuthenate) 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, 0.18 and 0.26% for the nasopharyngeal (head), tracheobronchial (TB) and pulmonary regions of the respiratory tract, respectively. Hence, very little airborne substance (<1%) is expected to deposit in the lower regions of the human respiratory tract, i.e. the TB or pulmonary regions via oronasal normal augmenter breathing. Most of the inhaled fraction is likely to be retained in the head region and therefore would be cleared by ingestion. Particles deposited in the TB region are also largely translocated to the gastrointestinal tract, and oral bioavailability will again predominantly determine systemic uptake. Thus, inhalation will not be a significant route of exposure. Further, tetraammonium decachloro-mu-oxodiruthenate is classified as a skin sensitiser. Given that skin sensitisation may be acquired by other routes of exposure than dermal, appropriate risk management measures/operational controls (RMMs/OCs) are required. These will ensure that the potential for inhalation exposure is minimised. Finally, for animal welfare reasons, conducting new in vivo toxicity tests is considered a last resort. Consequently, no testing by the inhalation route is considered justified.

5.2.1.3. Acute toxicity: dermal

No relevant information available.

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: other justification

Justification: See 'Remark' - 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. 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, tetraammonium decachloro-mu-oxodiruthenate is classified as a skin sensitiser (category 1B) and is allocated to the "moderate" hazard band (for local effects following acute and long-term dermal). 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 GLP study, the acute oral LD50 value for tetraammonium decachloro-mu-oxodiruthenate was calculated to be 3110 mg/kg bw following gavage administration in female rats (Haferkorn, 2016).

No relevant acute dermal or inhalation toxicity data were identified.

Value used for CSA:
Acute oral toxicity: no adverse effect observed (LD50) 3110 mg/kg bw
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 tetraammonium decachloro-mu-oxodiruthenate 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 corn oil) at doses of 550 (1 animal), 1750 (3 animals) or 5000 (3 animals) mg/kg body weight. Macroscopic examination was conducted on surviving animals. There were no deaths, clinical signs, or effects on growth during the 14-day observation period for animals in the 550 and 1750 mg/kg bw dose groups. In the high dose group (5000 mg/kg bw) however, all 3 animals died within 4 days of administration of the test material and clinical signs of toxicity were apparent in one animal. There were no notable external or internal macroscopic findings upon necropsy in any of the treated animals. The acute oral median lethal dose (LD50) of tetraammonium decachloro-mu-oxodiruthenate was calculated to be 3110 mg/kg bw using the Acute Oral Toxicity (OECD Test Guideline 425) Statistical Programme (AOT 425 Stat Pgm) software (Haferkorn, 2016).

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 CLP 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, tetraammonium decachloro-mu-oxodiruthenate 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	GHS criteria not met % tissue viability - Time	1 (reliable without restriction)

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 Guideline 439 (In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method) ; 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] ; 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). The test is designed to predict and classify the skin irritant potential of chemicals according to chemical safety regulations, using the reconstructed human epidermis model EPISKIN-SM and parameters related to skin irritation. EPISKIN-SM 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. Cell viability determination is based on cellular mitochondrial dehydrogenase activity, measured by MTT reduction and	point: 42 hours mean of 3 replicates. Value: 86 (no indication of irritation)	key study experimental study **Test material** 85392-65-0 / 286-924-7; Diammonium hexachlororuthenateTetraammonium decachloro-µ-oxodiruthenate; Tetraammonium decachloro-µ-oxodiruthenate (IV), Form: solid: particulate/powder - migrated information: powder **Reference** Hargitai J 2015

conversion into a blue formazan salt that is quantitatively measured after extraction from tissues. The reduction of cell viability in treated tissues is compared to negative controls and expressed as a %. The % reduction in viability is used to predict the irritation potential. The EPISKIN-SM has been found scientifically valid for reliably predicting no label and R38 (irritant) substances in respect to the previous EU classification scheme and has been confirmed in April 2009 by ESAC for use under the UN GHS system as “applicable to all authorities”. It is approved by international regulatory agencies as a replacement for the identification of irritants/corrosives in the in vivo rabbit skin assay (OECD 404).		

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)	Category 1 (irreversible effects on the eye) based on GHS criteria Initial pain reaction 2 (Time point: 0 hr) Based on this response, additional animals were not	1 (reliable without restriction) weight of evidence experimental study **Test material**

	treated chemosis score (mean) 2 of max. 4 (Time point: 24, 48 and 72 hours) not fully reversible within: 3 weeks Conjunctival discharge (mean) 3 of max. 3 (Time point: 24, 48 and 72 hours) not reversible Maximum-scoring discharge continued until the end of the observation period of 3 weeks Conjunctival redness (mean) 3 of max. 3 (Time point: 24, 48 and 72 hours) not fully reversible within: 3 weeks The conjunctivae were discoloured black by the test item; redness of 3.00 was assumed for the reading 24 hours after exposure cornea opacity score - opacity (mean) 1 of max. 4 (Time point: 24, 48 and 72 hours) not fully reversible within: 3 weeks iris score (mean) 0 of max. 2 (Time point: 24, 48 and 72 hours) No effects on the iris were reported	85392-65-0 / 286-924-7; Tetraammonium decachloro-µ-oxodiruthenate; Tetraammonium decachloro-µ-oxodiruthenate (IV), Form: solid: particulate/powder - migrated information: powder **Reference** Zelenák V 2015
in vitro study Chicken (isolated eyes only) (ROSS 308) Vehicle: None according to OECD Guideline 438 (Isolated Chicken Eye Test Method for Identifying Ocular	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	1 (reliable without restriction) weight of evidence experimental study **Test material** 85392-65-0 / 286-924-7;

Corrosives and Severe Irritants) [before 26 July 2013] 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 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).	mean of three values; value 1 cornea opacity score mean of three values; value 0.83 fluorescein retention score mean of three values; value 0.83	Tetraammonium decachloro-µ-oxodiruthenate, Form: solid: particulate/powder - migrated information: powder **Reference** Gönczöl K 2015

5.3.2.2. Human information

No relevant information available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No relevant information available

5.3.3.2. Human information

No relevant information available.

5.3.4. Summary and discussion of irritation

The following information is taken into account for any hazard / risk assessment:
In an in vitro reconstructed human epidermis (EpiSkin) assay, conducted in accordance with OECD Test Guideline 439 and to GLP, tetraammonium decachloro-μ-oxodiruthenate was considered to be non-irritating to skin (Hargitai, 2015).

In an OECD Test Guideline 405 study, to GLP, tetraammonium decachloro-μ-oxodiruthenate (0.1 g) caused immediate significant conjunctival and corneal irritant effects in the eye of a single male rabbit, which were not fully reversible within 3 weeks (Zelenák, 2015).

No relevant respiratory tract irritation data were identified.

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

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

Tetraammonium decachloro-μ-oxodiruthenate was tested for skin irritation potential in an in vitro reconstructed human epidermis model (EpiSkin assay) conducted in accordance with OECD Test Guideline 439, 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. Cell viability determination is based on cellular mitochondrial dehydrogenase activity, measured by MTT reduction and conversion into a blue formazan salt that is quantitatively measured after extraction from tissues. The reduction of cell viability in treated tissues is compared to negative controls and expressed as a %. If the resulting mean relative viability (as

adjusted for intrinsic colour) is less than or equal to 50% of the negative control, the test substance is considered to be irritant to skin. 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 86% and the range was 85 -86%), and it was therefore considered to be non-irritating to skin (Hargitai, 2015).

In an in vitro eye irritation study in isolated chicken eyes, conducted in accordance with OECD Test Guideline 438, tetraammonium decachloro-µ-oxodiruthenate appeared to be not severely irritating or corrosive and not to require a classification as a severe eye irritant. However, irritation criteria indicate that it may be (borderline) slightly irritating to the eye, and it remained adhered to the corneal surface after the post-treatment rinse (Gönczöl, 2015). As such, an in vivo study was conducted 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 tetraammonium decachloro-µ-oxodiruthenate was instilled into the conjunctival sac of the left eye of a single male New Zealand White rabbit. Following instillation the eyelids were held closed for several seconds; rinsing with physiological saline was performed at 24 and 48 hours, and after 1 and 2 weeks. 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, 2 and 3 weeks after treatment, and scored according to the Draize system. Immediate significant conjunctival and corneal irritant effects were observed within one hour that persisted at 72 hours and were not fully reversible within the 3-week observation period (Zelenák, 2015).

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 irritation study and the (in vivo and in vitro) eye irritation studies, tetraammonium decachloro-µ-oxodiruthenate does not require classification for skin irritation, but should be classified for serious eye damage (category 1), according to EU CLP criteria (EC 1272/2008).

5.4. Corrosivity

5.4.1. Non-human information

No relevant information available.

5.4.2. Human information

No relevant information available.

5.4.3. Summary and discussion of corrosion

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

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

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

Table 5.4. Studies on skin sensitisation

Method	Results	Remarks
mouse (CBA/CaOlaHsd) female skin sensitisation: in vivo (LLNA) according to OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay)	Category 1B (indication of skin sensitising potential) based on GHS criteria Stimulation index: (Negative control (propylene glycol): 1.0 Tetraammonium-decachloro-mu-oxodiruthenate 10%: 1.2 Tetraammonium-decachloro-mu-oxodiruthenate 25%: 1.5 Tetraammonium-decachloro-mu-oxodiruthenate 50%: 7.9 Positive control (HCA 25% in propylene glycol): 9.5) disintegrations per minute (DPM): (see Remark - Negative control (propylene glycol): mean 116.6 dpn (disintegrations per node, i.e. disintegrations per minute (dpm) divided by 2 (2 lymph nodes per animal)) (range 63.3-161.3) Tetraammonium-decachloro-mu-oxodiruthenate 10%: mean 141.4 dpn (range 85.3-241.3) Tetraammonium-decachloro-mu-oxodiruthenate 25%: mean 175.1 dpn (range 57.3-322.3) Tetraammonium-decachloro-mu-	1 (reliable without restriction) key study experimental study **Test material** 85392-65-0 / 286-924-7; Tetraammonium-decachloro-mu-oxodiruthenate, Form: solid: particulate/powder - migrated information: powder **Reference** Váliczkó E 2015

	oxodiruthenate 50%: mean 925.9 dpn (range 72.3-2255.8) Positive control (HCA 25% in propylene glycol): mean 1102.7 dpn (range 817.3-1675.8))	

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 already available.

5.5.1.2. Human information

No relevant information available.

5.5.2. Respiratory system

5.5.2.1. Non-human information

No relevant information available.

5.5.2.2. Human information

No relevant information available.

5.5.3. Summary and discussion of sensitisation

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

Skin sensitisation

In a mouse local lymph node assay (LLNA), conducted according to OECD Test Guideline 429 and to GLP, tetraammonium-decachloro-mu-oxodiruthenate induced a stimulation index of above 3 (calculated EC3 value of 30.9%) indicating a skin sensitising potential (Váliczkó, 2015).

No respiratory tract sensitisation data are available.

Value used for CSA: adverse effect observed (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 sensitisation potential of tetraammonium-decachloro-mu-oxodiruthenate was evaluated in a mouse LLNA, conducted in accordance with OECD Test Guideline 429 and to GLP. Following a preliminary irritation and toxicity test, in which a maximum concentration of 50% (w/v) was established for the main test, female mice (5/group) were topically treated on three consecutive days with 25 µl/ear of vehicle (propylene glycol), test material at 10, 25 or 50%, or positive control (hexyl cinnamaldehyde (HCA)). After three days without treatment, cell proliferation was measured by incorporation of 3H-methyl thymidine and the values obtained were used to calculate stimulation indices. There was no mortality, no overt toxicity and no sign of irritation at the application sites. Stimulation indices were 1.2, 1.5 and 7.9 for 10, 25 and 50% (w/v) tetraammonium-decachloro-mu-oxodiruthenate, respectively. In the absence of confounding effects (irritation or systemic toxicity), the proliferation values are considered to reflect sensitising potential. The EC3 value for tetraammonium-decachloro-mu-oxodiruthenate was 30.9% (w/v). The stimulation index for the positive control was 9.5. Hence, under the conditions of this assay, tetraammonium-decachloro-mu-oxodiruthenate was considered to have skin sensitising potential (Váliczkó, 2015).

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, tetraammonium-decachloro-mu-oxodiruthenate should be classified as a skin sensitiser (category 1B), according to EU CLP criteria (EC 1272/2008).

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of studies are summarised in the following table:

Table 5.5. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks
rat [common rodent species] (Crl:CD(SD)) male/female repeated dose toxicity: oral, other - Part of a combined repeated dose study (OECD 422) with reproductive and developmental toxicity screening. (oral: gavage) 100mg/kg bw/day (nominal) 300mg/kg bw/day (nominal) 1000mg/kg bw/day (nominal) Vehicle: corn oil Exposure: Males and females were dosed from 2 weeks prior to mating and during the mating period. Males were further dosed after the mating period for a total treatment duration of 34 days. Females were dosed throughout gestation and at least up to and including day 13 post-partum (total of 40-55 days). (Daily) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	NOAEL: 300 mg/kg bw/day (nominal) (male/female) based on: (test mat.) clinical signs ; mortality ; body weight and weight gain ; food consumption and compound intake	1 (reliable without restriction) key study experimental study **Test material** Tetraammonium-decachloro-μ-oxodiruthenate / 85392-65-0, Form: solid **Reference** Hansen B 2017

5.6.1.2. Repeated dose toxicity: inhalation

No relevant information available.

5.6.1.3. Repeated dose toxicity: dermal

No relevant information available.

5.6.1.4. Repeated dose toxicity: other routes

No relevant information available.

5.6.2. Human information

No relevant information available.

5.6.3. Summary and discussion of repeated dose toxicity

The following information is taken into account for any hazard / risk assessment:
Key Information:
In an OECD Test Guideline 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of tetraammonium-decachloro-mu-oxodiruthenate for at least 34 days, no clinical signs of toxicity or any adverse pathological or histopathological effects were observed at up to 300 mg/kg bw/day (Hansen, 2017).

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

Value used for CSA (via oral route - systemic effects):
no adverse effect observed (NOAEL): (300 mg/kg bw/day) (subacute); (rat [common rodent species])

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

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

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

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

Additional information:
No relevant human data were identified.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, CD rats (10/sex/group) were orally administered tetraammonium-decachloro-mu-oxodiruthenate by stomach tube (gavage) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for 34 days (14 days pre-mating, as well as during the mating and post-mating periods). Females were dosed for 14 days pre-mating, through mating,

gestation (around 22 days) and up to post-natal day 13 (40-55 days in total). Premature death and body weight losses (as well as various clinical signs) were reported for the high dose group (1000 mg/kg bw/day), leading to the termination of these animals after only 2 weeks of treatment. Tetraammonium-decachloro-mu-oxodiruthenate did not result in test item related mortality, clinical signs of toxicity, neurological observations, or changes in the body weight, food consumption, haematology or clinical chemistry parameters at up to 300 mg/kg bw/day during the treatment period. There were no adverse treatment-related changes in organ weights, or following macroscopic examination and histopathology for the adult animals of either sex, aside from some local effects on the stomach at the mid dose (also observed in prematurely terminated animals at the high dose). On this basis, a study NOAEL of 300 mg/kg bw/day was established (Hansen, 2017).

According to REACH Annex VIII (EC 1907/2006), repeated dose toxicity studies only need to be conducted on one species taking into consideration the most appropriate route of administration regarding human exposure. 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:
In a reliable repeated dose toxicity study (combined with a reproductive/developmental screening assay) involving gavage administration of tetraammonium-decachloro-mu-oxodiruthenate to rats for at least 34 days, no adverse systemic effects were seen at up to 300 mg/kg bw/day. As such, classification of this substance as STOT-RE is not required, according to EU CLP criteria (EC 1272/2008). The observed effects on the stomach are likely the result of local irritancy.

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

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

Table 5.6. 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	Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 [bacteria];	1 (reliable without restriction) key study experimental study

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: 5, 16, 50, 160, 500, 1600 and 5000 µg/plate Experiment 1: 5, 16, 50, 160, 500, 1600 and 5000 µg/plate Experiment 2: 20.48, 51.2, 128, 320, 800, 2000 and 5000 µg/plate Positive control substance(s): 2-nitrofluorene Positive control substance(s): sodium azide Positive control substance(s): 9-aminoacridine Positive control substance(s): mitomycin C Positive control substance(s): benzo(a)pyrene Positive control substance(s): 2-aminoanthracene Positive control substance(s): 2-aminoanthracene according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	met. act.: with and without genotoxicity: negative cytotoxicity: yes Experiment 1 (plate incorporation protocol): at 500 µg/plate, without S9; at 1600 µg/plate, with S9) Experiment 2: at 2000 µg/plate, without S9 (plate incorporation); at 5000 µg/plate, with S9 (pre-incubation)) vehicle controls valid: yes negative controls valid: not applicable positive controls valid: yes Test results: negative for S. typhimurium TA 102 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: yes Experiment 1 (plate incorporation protocol): at 500 µg/plate, without S9; at 1600 µg/plate, with S9) Experiment 2: at 2000 µg/plate, without S9 (plate incorporation); at 5000 µg/plate, with S9 (pre-incubation)) vehicle controls valid: yes negative controls valid: no positive controls valid: yes	**Test material** 85392-65-0 / 286-924-7; Tetraammonium-decachloro-mu-oxodiruthenate, Form: solid: particulate/powder - migrated information: powder **Reference** McGarry S 2016
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: yes	1 (reliable without restriction) key study experimental study **Test material** 85392-65-0 / 286-

Test concentrations: Cytotoxicity range-finder experiment: 62.5, 125, 250, 500, 1000 and 2000 µg/mL (both with and without S9) Experiment 1: 100, 200, 400, 600, 800, 1000 and 1200 µg/mL (without S9) and 100, 200, 400, 600, 800, 1000, 1200, 1400, 1600 and 1800 µg/mL (with S9) Experiment 2: 125, 250, 500, 750, 1000, 1200 and 1400 µg/mL (with and without S9) 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]	The highest concentrations analysed in experiment 1 (1200 (-S9) and 1800 (+S9) µg/mL) gave 100 and 69% RS respectively. The highest concentrations analysed in experiment 2 (1400 µg/mL, - and +S9) gave 25 and 27% RS respectively. vehicle controls valid: yes negative controls valid: not applicable positive controls valid: yes	924-7; Tetraammonium-decachloro-mu-oxodiruthenate. Form: solid: particulate/powder - migrated information: powder **Reference** Lloyd M 2016
in vitro mammalian cell micronucleus test [in vitro cytogenicity / micronucleus study] (in vitro cytogenicity / micronucleus study - Type of genotoxicity: chromosome aberration) lymphocytes: human, whole blood [primary culture] (Met. act.: with and without) Test concentrations: Range-finder experiment: 7.256-2000 µg/mL Micronucleus experiment (3+21): 25-750 µg/mL Micronucleus experiment (24+0): 50-1000 µg/mL Positive control substance(s): mitomycin C	Test results: negative - 3+21 hours -/+S9; 24+0 hours -S9 for lymphocytes: human, whole blood [primary culture]; met. act.: with and without genotoxicity: negative - 3+21 hours -/+S9; 24+0 hours -S9 cytotoxicity: no, but tested up to precipitating concentrations vehicle controls valid: yes negative controls valid: not applicable positive controls valid: yes	1 (reliable without restriction) key study experimental study **Test material** 85392-65-0 / 286-924-7; Tetraammonium-decachloro-mu-oxodiruthenate, Form: solid: particulate/powder - migrated information: powder **Reference** Lloyd M 2016

Positive control substance(s): cyclophosphamide Positive control substance(s): noscapine according to OECD Guideline 487 (2014). In Vitro Mammalian Cell Micronucleus Test		

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, tetraammonium-decachloro-mu-oxodiruthenate 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 a rat liver metabolic activation system (S9) (McGarry, 2016).

In an in vitro mammalian cell gene mutation assay, conducted in accordance with OECD Test Guideline 476 and to GLP, tetraammonium-decachloro-mu-oxodiruthenate did not induce biologically relevant increases in mutations at the hprt locus of mouse lymphoma L5178Y cells when tested up to precipitating concentrations in the absence and presence of S9 (Lloyd, 2016a).

In an in vitro micronucleus assay, conducted according to OECD Test Guideline 487 and to GLP, tetraammonium-decachloro-mu-oxodiruthenate failed to induce increases in micronuclei in cultured human peripheral blood lymphocytes when tested up to the limit of solubility, for 3 hours in the absence and presence of S9, and for 24 hours without S9 (Lloyd, 2016b).

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

Justification for classification or non classification
Based on the existing in vitro genotoxicity data set, tetraammonium-decachloro-mu-oxodiruthenate does not meet the criteria for classification as a germ cell mutagen (category 1A or 1B) under EU CLP criteria (EC 1272/2008).

Additional information:
Tetraammonium-decachloro-mu-oxodiruthenate 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 (each in triplicate): in experiment 1, a plate incorporation protocol was used; the experiment was repeated, using an additional pre-incubation step for the test with S9. 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. Appropriate vehicle and positive control cultures were included in the test system under each treatment condition and fit the acceptance criteria. There was no evidence of mutagenicity in any strain with or without S9 in either experiment. There was some evidence of toxicity at 500-5000 µg/plate with the plate incorporation protocol and at 2000-5000 µg/plate with the pre-incubation protocol. Vehicle and positive controls performed as expected. It is concluded that tetraammonium-decachloro-mu-oxodiruthenate 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, 2016).

In an in vitro GLP study, conducted in accordance with OECD Test Guideline 476 (in vitro mammalian cell gene mutation assay), tetraammonium-decachloro-mu-oxodiruthenate 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 (62.5-2000 µg/mL) were tested (with and without S9); precipitation was seen after 3 hours incubation at the highest concentration. In the main test, cells were exposed to test material for 3 hr in two independent experiments, each in the absence and presence of a rat liver metabolic activation system (S9). The highest concentrations analysed, limited by precipitation, were 1200 µg/mL and 1800 µg/mL (Experiment 1, without and with S9, respectively) exhibiting 100% and 69% relative survival (RS), respectively. In Experiment 2, the highest concentrations analysed was

1400 µg/mL, both without and with S9), which gave RS values of 25% and 27%, respectively. No significant increases in mutant frequency (MF) over the concurrent controls were observed following treatment with tetraammonium-decachloro-mu-oxodiruthenate at any concentration analysed in the absence and presence of S9 in Experiment 1 and in the presence of S9 in Experiment 2. Although a statistically significant increase in MF was observed at the highest concentration analysed in the absence of S9 in Experiment 2 (1400 µg/mL), this was considered not biologically relevant since the concurrent vehicle control MF was low compared with the historical control and there was a lack of reproducibility between experiments. The statistically significant linear trends observed in both experiments were also considered not biologically relevant. Overall, tetraammonium-decachloro-mu-oxodiruthenate did not induce biologically relevant increases in gene mutations at the hprt locus of L5178Y mouse lymphoma cells, when tested up to the limits of solubility in two independent experiments, each in the presence and absence of S9 (Lloyd, 2016a).

Tetraammonium-decachloro-mu-oxodiruthenate was tested for its ability to induce chromosome damage (micronuclei) in human peripheral blood lymphocytes in an assay conducted in accordance with OECD Test Guideline 487 and to GLP. The highest concentrations of test article analysed were limited by precipitation and were determined following a preliminary range-finder experiment. Cells were treated with the test material (at up to 400 µg/plate, the limit of solubility) for either 3 hours (with 21 hours recovery time) in the presence and absence of S9, or for 24 hours without S9. Appropriate vehicle and positive control cultures were included in the test system under each treatment condition and matched the acceptance criteria. There was no evidence of an increase in micronucleus frequency with or without S9 following treatment of cells with tetraammonium-decachloro-mu-oxodiruthenate for 3 hours and/or 24 hours. Some evidence of cytotoxicity was observed at 100 µg/mL without S9, but none with S9. Vehicle and positive controls performed as expected. Overall, tetraammonium-decachloro-mu-oxodiruthenate did not induce increases in the frequency of micronuclei in human peripheral blood lymphocytes treated in culture, when tested up to the limit of solubility in the presence and absence (3-hour treatment) or absence (24-hour treatment) of S9 (Lloyd, 2016b).

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 5.7. Studies on fertility

Method	Results	Remarks
rat (Crl:CD(SD)) male/female screening for reproductive / developmental toxicity - Part of a combined repeated dose study (OECD 422) with reproductive and developmental toxicity screening. oral: gavage 100mg/kg bw/day (nominal) “Low dose”	**First parental generation (P0)** NOAEL - Fertility and reproductive parameters (PO) 300 mg/kg bw/day (nominal)) (male/female) based on: reproductive performance [reproductive toxicity] **Second parental generation (P1)** **F1 generation** NOAEL - Pre- and post-natal	1 (reliable without restriction) key study experimental study **Test material** Tetraammonium-decachloro-µ-oxodiruthenate / 85392-65-0

300mg/kg bw/day (nominal) “Mid dose” 1000mg/kg bw/day (nominal) “High dose” Vehicle: corn oil Exposure: Males and females were dosed from 2 weeks prior to mating and during the mating period. Males were further dosed after the mating period for a total treatment duration of 34 days. Females were dosed throughout gestation and at least up to and including day 13 post-partum (total of 40-55 days). (Daily) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	development of pups (PO): 300 mg/kg bw/day (nominal) (male/female) based on: no effects at mid dose (high dose parental animals were prematurely terminated)	Form: solid **Reference** Hansen B 2017

5.9.1.2. Human information

No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

See section 5.9.1 above, for the results of a OECD Test Guideline 422 combined repeated dose and reproductive/developmental toxicity screening study in rats.

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 tetraammonium-decachloro-mu-oxodiruthenate for at least 34 days, no effects on any measured reproductive or fertility parameters, or microscopic changes in the reproductive organs, were observed at up to 300 mg/kg bw/day (Hansen, 2017).

Value used for CSA (route: oral):

no adverse effect observed (NOAEL) 300 mg/kg bw/day (subacute); (rat [common rodent species])

Value used for CSA (route: dermal):

no study available

Value used for CSA (route: inhalation):

no study available

Additional information:

No relevant data in humans were identified.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, CD rats (10/sex/group) were orally administered tetraammonium-decachloro-mu-oxodiruthenate by stomach tube (gavage) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for 34 days (14 days pre-mating, as well as during the mating and post-mating periods). Females were dosed for 14 days pre-mating, through mating, gestation (around 22 days) and up to post-natal day 13 (40-55 days in total). Premature death and body weight losses (as well as various clinical signs) were reported for the high dose group (1000 mg/kg bw/day), leading to the termination of these animals after only 2 weeks of treatment. There were no reported changes to reproductive parameters (including number of implantation sites, number of pups, fertility and gestation indices, reproductive performance as well as pre- and post-implantation losses). Further, no treatment-related microscopic changes were observed in the reproductive organs. The systemic and reproductive NOAEL was 300 mg/kg bw/day (Hansen, 2017).

Developmental toxicity

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

In an OECD Test Guideline 422 combined repeated dose and reproductive/developmental toxicity screening study in rats, involving the gavage administration of tetraammonium-decachloro-mu-oxodiruthenate for at least 34 days, no developmental effects were observed. The systemic and developmental NOAEL was 300 mg/kg bw/day (Hansen, 2017).

Value used for CSA (route: oral):
no adverse effect observed (NOAEL) 300 mg/kg bw/day (subacute); (rat [common rodent species])

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

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

Additional information:
No relevant data in humans were identified.

In a combined repeated dose toxicity and reproductive/developmental toxicity screening study, conducted according to OECD Test Guideline 422 and to GLP, CD rats (10/sex/group) were orally administered tetraammonium-decachloro-mu-oxodiruthenate by stomach tube (gavage) at doses of 0, 100, 300 or 1000 mg/kg bw/day. Males were dosed for 34 days (14 days pre-mating, as well as during the mating and post-mating periods). Females were dosed for 14 days pre-mating, through mating, gestation (around 22 days) and up to post-natal day 13 (40-55 days in total). Premature death and body weight losses (as well as various clinical signs) were reported for the high dose group (1000 mg/kg bw/day), leading to the termination of these animals after only 2 weeks of treatment. There were no adverse effects on the F1 offspring viability, growth or developmental effects. The systemic and developmental NOAEL was 300 mg/kg bw/day (Hansen, 2017).

Justification for classification or non classification:
In a reliable combined repeated dose toxicity study and reproductive/developmental toxicity screening study involving gavage administration of tetraammonium-decachloro-mu-oxodiruthenate to rats for at least 34 days, no adverse effects on reproductive parameters (sexual function or fertility) or development of offspring were seen at up to 300 mg/kg bw/day. As such, classification of this substance 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

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

5.11.1. Overview of typical dose descriptors for all endpoints

Table 5.8. Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type
Acute toxicity	oral	no adverse effect observed (LD50): 3110 mg/kg bw
Acute toxicity	dermal	no study available
Acute toxicity	inhalation	no study available
Irritation / Corrosivity	skin	no adverse effect observed (not irritating)
Irritation / Corrosivity	eye	adverse effect observed (irreversible damage)
Irritation / Corrosivity	resp. tract	no study available
Sensitisation	skin	adverse effect observed (sensitising)
Sensitisation	resp. tract	no study available
Repeated dose toxicity	oral	no adverse effect observed (NOAEL): 300 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): 300 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): 300mg/kg bw/day (subacute; rat [common rodent species])
Reproductive toxicity: developmental toxicity	dermal	no study available
Reproductive toxicity: developmental toxicity	inhalation	no study available

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

Table 5.9. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.28 mg/m³	repeated dose toxicity (Oral)
Inhalation	Systemic effects - Acute	no hazard identified	
Inhalation	Local effects - Long-term	medium hazard (no threshold derived)	sensitisation (skin)

Inhalation	Local effects - Acute	medium hazard (no threshold derived)	sensitisation (skin)
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.4mg/kg bw/day	repeated dose toxicity (Oral)
Dermal	Systemic effects - Acute	no hazard identified	
Dermal	Local effects - Long-term	medium hazard (no threshold derived)	sensitisation (skin)
Dermal	Local effects - Acute	medium hazard (no threshold derived)	sensitisation (skin)
Eyes	Local effects	medium hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEC

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

Overall Assessment Factor: 75

AF for dose response relationship: 1 (Default ECHA AF; NOAEL from a well-conducted oral combined repeated-dose with reproductive/developmental toxicity screening study)

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

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

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

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

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

AF for remaining uncertainties: 1 (Not required)

Further explanation on hazard conclusions:

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

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

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

Inhalation Local effects - Long-term

Further explanation on hazard conclusions:

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

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

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

Dermal Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEL

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

Overall Assessment Factor: 75

AF for dose response relationship: 1 (Default ECHA AF; NOAEL from a well-conducted oral combined repeated-dose with reproductive/developmental toxicity screening study)

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

AF for interspecies differences (allometric scaling): 1 (Default ECHA AF for rat for toxicokinetic

differences in metabolic rate (allometric scaling) is not required)

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

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

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

AF for remaining uncertainties: 1 (Not required)

Further explanation on hazard conclusions:

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

Dermal Systemic effects - Acute

Further explanation on hazard conclusions:

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

Dermal Local effects - Long-term

Further explanation on hazard conclusions:

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

Dermal Local effects - Acute

Further explanation on hazard conclusions:

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

Discussion:

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

As no relevant data on effects of repeated inhalation exposure to tetraammonium decachloro-mu-oxodiruthenate 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 tetraammonium decachloro-mu-oxodiruthenate for at least 34 days, no clinical signs of toxicity or any adverse pathological or

histopathological effects (including the reproductive organs) were observed at up to 300 mg/kg bw/day (aside from some local effects on the stomach). [Premature death and body weight losses (as well as various clinical signs) were reported for the high dose group (1000 mg/kg bw/day), leading to the termination of these animals after only 2 weeks of treatment.] No effects on reproductive parameters, indications of maternal/foetal toxicity, or developmental effects were observed at any dose level. Thus, the NOAEL for systemic, reproductive and developmental toxicity was 300 mg/kg bw/day (Hansen, 2017). This equates to a NOAEL of 86.68 mg/kg bw/day when expressed as elemental ruthenium based on MWt ratios[1], and is considered protective of general systemic effects, fertility and developmental toxicity.

The dataset for toxicokinetics of ruthenium and its salts is very limited, with most studies investigating the simple salt ruthenium (III) chloride (RuCl3) hydrate. In a series of studies, covering oral, intraperitoneal and intravenous administration to rodents, dogs and primates, the toxicokinetic profile of RuCl3 was found to be fairly consistent between the species. Oral absorption was low (up to around 3%) (Furchner et al., 1971).

In another study, radiolabelled 103RuCl3 was administered to a single, healthy male volunteer by contamination of edible clams. About 3 µCi of radiation was administered, and the distribution of the tracer was followed by a whole body scanner for 58 days. Only 1% of the administered dose was considered to be absorbed, with a half-life of 30 days. Absorption of chloro-nitrosyl ruthenium (III) complexes was found to be approximately 3-times that of simple chlorinated ruthenium (III) or (IV) complexes (Yamagata et al., 1969).

No good-quality data were found regarding absorption of ruthenium compounds following inhalation. Particle size distribution (PSD) data, as measured by simple sieving, indicate that none of the tetraammonium decachloro-mu-oxodiruthenate 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 (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, 0.18 and 0.26% 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. As a water soluble substance (20-30 g/L; Gregory, 2012; 2014), any tetraammonium decachloro-mu-oxodiruthenate reaching the lungs is likely to be absorbed through aqueous pores or be retained in the mucus and transported out of the respiratory tract.

[1] MWts: Ru metal, 101.1 g mol-1; Tetraammonium decachloro-mu-oxodiruthenate, 349.9 g mol-1

Therefore, for this oral-to-inhalation extrapolation, a figure of 1% oral absorption has been used, taken from the laboratory study in man. In line with the guidance (ECHA, 2012), the worst-case of 100% absorption after inhalation has still been assumed for the 'end' route.

Corrected inhalatory NOAEC (worker, 8 h exposure/day) = oral NOAEL*(1/sRv[rat])*(ABS[oral-rat]/ABS[inh-human]) *(sRV[human]/wRV) = 300 mg/kg bw/day*(1/0.38 m3/kg bw/day)*(1/100)*(6.7 m3 [8h]/10 m3 [8h]) = 5.29 mg/m3

It is noted that the standard respiratory rate conversion figure (0.38 m3/kg bw/day) already incorporates a factor of 4 for allometric scaling from rat to human. An assessment factor (AF) for allometric scaling is not considered to be justified in this scenario, given that 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 = 5.29*4 = 21.2 mg/m3

Application of the appropriate assessment factors (overall AF 75) to this corrected inhaled NOAEC gives a systemic long-term inhalation DNEL for tetraammonium decachloro-mu-oxodiruthenate of 0.28 mg/m*3*. This equates to an elemental ruthenium exposure of 0.082 mg/m3.

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

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

There are no data in relation to acute inhalation or dermal exposure to tetraammonium decachloro-mu-oxodiruthenate. In a guideline (OECD TG 425) acute oral toxicity study in female rats, the LD*50* value was calculated to be 3110 mg/kg bw (Haferkorn, 2016). 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, 2016a). However, tetraammonium decachloro-mu-oxodiruthenate 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 tetraammonium

decachloro-mu-oxodiruthenate in humans or laboratory animals. Consequently, no worker-DNELs for long-term or acute local effects in the respiratory tract have been calculated.
However, according to ECHA (2016a) guidance (Part E), “since sensitisation is essentially systemic in nature, it is important for the purposes of risk management to acknowledge that skin sensitisation may be acquired by other routes of exposure than dermal. There is therefore a need for cautious use of known contact allergens in products to which consumers or workers may be exposed by inhalation”. Tetraammonium decachloro-mu-oxodiruthenate is classified as a moderate skin sensitiser. Therefore, consider recommended Risk Management Measures/Operational Conditions (RMMs/OCs) in Table E.3-1 of ECHA (2016a).

Hazard via dermal route: systemic effects following long-term exposure
As no relevant data on effects of repeated dermal exposure to tetraammonium decachloro-mu-oxodiruthenate 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”] (Hansen, 2017).

The oral NOAEL of 300 mg/kg bw/day equates to a NOAEL of 86.68 mg/kg bw/day for elemental ruthenium (based on MWt ratios), and is considered protective of general systemic effects, 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. Therefore, for this oral-to-dermal extrapolation, a figure of 1% oral absorption has been used based on experimental data in man (Yamagata et al., 1969).
No substance-specific data on dermal uptake of tetraammonium decachloro-mu-oxodiruthenate were identified. The “high” water solubility (> 10 g/L) suggests that the substance may be too hydrophilic to cross the lipid-rich environment of the stratum corneum to a significant extent, indicating that a low default value for dermal absorption is appropriate in this case; 10% is the lower of the two values provided by the guidance (ECHA, 2014). However, in vitro permeation studies on soluble platinum and rhodium salts generally showed a lower degree of absorption [around 1%] than this default would assume. It is reasonable to expect ruthenium and its salts to behave similarly.

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). There is no evidence that tetraammonium decachloro-mu-oxodiruthenate causes skin irritation (which could facilitate a

greater degree of dermal uptake) (Hargitai, 2015). Overall, 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]) = 300 mg/kg bw/day*(1%/10%) = 30 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 tetraammonium decachloro-mu-oxodiruthenate of 0.4 mg/kg bw/day, which equates to an elemental ruthenium exposure of 0.12 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 tetraammonium decachloro-mu-oxodiruthenate, 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 (Hargitai, 2015).

In another guideline (OECD TG 429) study, tetraammonium decachloro-mu-oxodiruthenate induced skin sensitisation in the mouse local lymph node assay (LLNA). The calculated Effect Concentration 3 (EC3) value was 30.9% (Váliczkó, 2015). Consequently, the compound is classified for skin sensitisation as Category 1B, under CLP.

According to ECHA (2016a) guidance “moderate skin sensitisers (classified in Sub-category 1B in CLP) are allocated to the moderate hazard category band on the basis that exposure to these moderate skin sensitising substances should be well-controlled”. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2016a).

Hazard for the eyes

In a guideline (OECD TG 405) eye irritation study, tetraammonium decachloro-mu-oxodiruthenate produced immediate significant conjunctival and corneal irritant effects in the eye of a single male rabbit, which were irreversible within 3 weeks (Zelenák, 2015). In a previously conducted in vitro isolated chicken eye irritation study (OECD TG 438), the substance was not severely irritating or corrosive (Gönczöl, 2015). Overall, the compound is classified for eye effects in category 1 under EU CLP.

No dose-response data was available from which to derive a DNEL, therefore a qualitative assessment was considered appropriate. Substances classified for serious eye damage (Category 1 in CLP) should be allocated to the “moderate hazard band on the basis that exposure to such corrosives, eye damaging or irritant substances should be well-controlled”. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2016a).

Table 5.10. Hazard conclusions for the general population

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

	Long-term	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 tetraammonium decachloro-mu-oxodiruthenate, 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, tetraammonium decachloro-mu-oxodiruthenate 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 (2016b), an assessment of indirect exposure of humans via the environment for tetraammonium decachloro-mu-oxodiruthenate 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

No relevant information available.

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: Tetraammonium decachloro-mu-oxodiruthenate(4-) (Boundary composition)

Related composition: Tetraammonium decachloro-mu-oxodiruthenate(4-) (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 6.1. 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) Remarks: The pile failed to ignite during the two minutes that the Bunsen flame was applied.	1 (reliable without restriction) key study experimental study **Test material** Tetraammonium decachloro-mu-oxodiruthenate (4-), **Reference** Tremain SP, Atwal SS 2011

Discussion

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

Flammability.

Key value for chemical safety assessment: Flammability: not classified

Tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.

Additional information:

Tremain and Atwal is a GLP compliant study following UN method N1 and is considered suitable for use as the key study for this endpoint. Tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as a readily combustible 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.

Classification according to GHS

Name: Tetraammonium decachloro-mu-oxodiruthenate(4-)

Related composition: Tetraammonium decachloro-mu-oxodiruthenate(4-) (Boundary composition) (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:

Tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as a readily combustible 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 6.2. Information on oxidising potential

Method	Results	Remarks
oxidising solids Contact with: powdered cellulose (3	Evaluation of results: GHS criteria not met	1 (reliable without restriction)

min) 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: 0 s (Pale grey smoke, the pile was slightly charred) 4:1 sample-to-cellulose ratio: mean burning time: 0 s (Pale grey smoke, no sign of ignition during the 3 minutes the power was applied.) reference: 3:7 mixture potassium bromate + cellulose: mean burning time: 136 s (An orange/blue spluttering flame which left dark grey ash) Remarks: The 4:1 and 1:1 test item:cellulose mixtures did not ignite and burn during the 3 minutes that the power was applied. This indicates that the test item is not an oxidising solid.	key study experimental study **Test material** Tetraammonium decachloro-mu-oxodiruthenate (4-), **Reference** Tremain SP, Atwal SS 2011

Discussion

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

Tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as an oxidising solid in accordance with CLP regulations.

Value used for CSA:

Oxidising properties: non oxidising

Additional information:

Tremain and Atwal (2011) is a GLP compliant study following UN method O.1 and is considered suitable for use as they key study for this endpoint. Tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as an oxidising solid 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: Tetraammonium decachloro-mu-oxodiruthenate(4-)

Related composition: Tetraammonium decachloro-mu-oxodiruthenate(4-) (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:

Based on the result of a GLP compliant study following UN method O.1, tetraammonium decachloro-mu-oxodiruthenate (4-) is not classified as a oxidising solids in accordance with CLP regulations.

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

Additional information:

Acute data are available for invertebrates (*Daphnia magna)*, fish (*Danio rerio*) and algae (*Pseudokirchneriella subcapitata*) exposed to tetraammonium-decachloro-µ-oxodiruthenate. An activated sludge respiration inhibition test has also been conducted to assess the toxicity of the test item to STP microorganisms. Based on the available data, algae are considered to be the most sensitive trophic level.

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
Danio rerio (previous name: *Brachydanio rerio*) freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test); according to EU Method C.1 (Acute Toxicity for Fish)	LC50 (96h): >75.19 mg/L test mat. - Tetraammonium decachloro-mu-oxodiruthenate (meas. (geom. mean)) based on: mortality LC50 (96h): >22.75 mg/L element - Ruthenium (meas. (geom. mean)) based on: mortality	1 (reliable without restriction) key study experimental study **Test material** Tetraammonium decachloro-mu-oxodiruthenate, Form: solid: particulate/powder **Reference** Teigeler M 2016

Discussion

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

The 96 hour LC50 is > 75.19 mg tetraammonium decachloro-mu-oxodiruthenate L^{-1} corresponding to >22.75 mg Ru L^{-1}.

Additional information:

Zebrafish (*Danio rerio*) were exposed to the test substance at a range of 5 test item concentrations for 96 hours under semi-static conditions (Teigeler 2016). The test was performed according to OECD guideline 203 and EC method C.1. Mortality and sub-lethal effects (including loss of equilibrium and change in swimming behaviour) were determined after 3, 24, 48, 72 and 96 hours. Test solutions were renewed after 48 hours, and fresh and aged test solutions were analysed by ICP-OES. Based on analysis of ruthenium, test concentrations were outside 80 – 120% of nominal, and therefore geometric mean measured concentrations were used for the reporting of results.

Neither significant signs of disease nor stress were observed at test concentrations up to 10.27 mg tetraammonium decachloro-mu-oxodiruthenate L^{-1}. Due to the dark colour of test media at concentrations 18.87 to 75.19 mg L^{-1}, it was not possible to adequately observe signs of disease or stress, but fish near the surface of the water were active. No fish died during the course of the study. The LC50 was determined to be > 75.19 mg tetraammonium decachloro-mu-oxodiruthenate L^{-1}, corresponding to > 22.75 mg Ru L^{-1}.

7.1.1.2. Long-term toxicity to fish

No relevant information available.

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 7.2. Short-term effects on aquatic invertebrates

Method	Results	Remarks
Daphnia magna freshwater semi-static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test); according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): >55.7 mg/L test mat. (meas. (TWA)) based on: mobility NOEC (48h): >=55.7 mg/L test mat. (meas. (TWA)) based on: mobility	1 (reliable without restriction) key study experimental study **Test material** Tetraammonium decachloro-µ-oxodiruthenate, Form: solid:

		particulate/powder **Reference** Simon M 2016

Discussion

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

Tetraammonium decachloro-µ-oxodiruthenate is not acutely toxic to *Daphnia magna* under the chosen test conditions. The NOEC is ≥ 55.7 mg L^{-1} (highest concentration tested) and the EC50 is > 55.7 mg L^{-1}, based on time-weighted mean measured test concentrations.

Additional information:

The influence of tetraammonium decachloro-µ-oxodiruthenate on immobilisation of *Daphnia magna* was investigated in a GLP-compliant study according to OECD Guideline 202 (Simon 2016). Daphnids were placed in dilution water containing the test item at nominal concentrations of 5.68, 11.4, 22.7, 45.5, and 100 mg test item L^{-1}. Test solutions were analysed for ruthenium using ICP-OES and as measured concentrations were outside 80 – 120% of nominal, time weighted mean measured concentrations of (2.94, 5.9, 12.1, 22.7 and 55.7 mg L^{-1}) were used for reporting of results. The test was conducted under semi-static conditions for 48 hours. Effects on immobilisation were determined after 24 and 48 hours.

No significantly increased mortality up to a TWM concentration of 55.7 mg test item L^{-1} (highest test concentration, corresponding to 100 mg L^{-1} nominal) was detected when compared to the control daphnids The NOEC is ≥ 55.7 mg L^{-1} (highest concentration tested) and the EC50 is > 55.7 mg L^{-1}, based on time-weighted mean measured test concentrations.

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	EC50 (72h): 0.38 mg/L test mat. (meas.	1 (reliable without

(previous names: *Raphidocelis subcapitata, Selenastrum capricornutum*) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test)	(geom. mean)) based on: growth rate (95% CL: 0.365 and 0.396 mg/L) EC50 (72h): 0.057 mg/L test mat. (meas. (geom. mean)) based on: yield (95% CL: 0.053 and 0.061 mg/L) NOEC (72h): 0.023 mg/L test mat. (meas. (geom. mean)) based on: growth rate NOEC (72h): 0.023 mg/L test mat. (meas. (geom. mean)) based on: yield EC10 (72h): 0.019 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95% CL: 0.017 and 0.020 mg/L) EC10 (72h): 0.016 mg/L test mat. (meas. (geom. mean)) based on: yield (95% CL: 0.013 and 0.019 mg/L) EC20 (72h): 0.052 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95% CL: 0.049 and 0.056 mg/L) EC20 (72h): 0.025 mg/L test mat. (meas. (geom. mean)) based on: yield (95% CL: 0.022 and 0.028 mg/L)	restriction) key study experimental study **Test material** Tetraammonium-decachloro-µ-oxodiruthenate, Form: solid: particulate/powder **Reference** Wenzel A 2016

Discussion

Effects on algae / cyanobacteria

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

The E_rC50 and E_rC10 values for inhibition of growth rate were 0.380 and 0.019 mg tetraammonium-decachloro-µ-oxodiruthenate L^{-1}, respectively. The E_yC50 and E_yC10 values for inhibition of yield were 0.057 and 0.016 mg tetraammonium-decachloro-µ-oxodiruthenate L^{-1}, respectively. The NOEC for both growth rate and yield was 0.023 mg tetraammonium-decachloro-µ-oxodiruthenate L^{-1}.

Additional information:

The 72-hour toxicity of tetraammonium-decachloro-µ-oxodiruthenate to the unicellular green *Pseudokirchneriella subcapitata* was determined in a static system following OECD guideline 201 (Wenzel 2016). Test solutions were analysed using ICP-OES and results reported based on mean measured concentrations, as measured concentrations deviated from nominal by more than 20%. Four replicate cultures were exposed to geometric mean concentrations of 0.023, 0.080, 0.292, 0.962, 2.95 and 10.3 mg test item L^{-1}. Eight control replicates were included.

There was a concentration-related growth inhibition and the E_rC50 and E_rC10 values for inhibition of growth rate were 0.380 and 0.019 mg tetraammonium-decachloro-µ-oxodiruthenate L^{-1}, respectively. The E_yC50 and E_yC10 values for inhibition of yield were 0.057 and 0.016 mg tetraammonium-decachloro-µ-oxodiruthenate L^{-1}, respectively. The NOEC for both growth rate and yield was 0.023 mg tetraammonium-decachloro-µ-oxodiruthenate L^{-1}.

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): 100 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate (Without ATU) NOEC (3h): 180 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (With ATU) EC10 (3h): 190 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate (160 -210 mg/L. Without ATU) EC10 (3h): 250 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (220 - 280 mg/L. With ATU) EC50 (3h): 500 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate (450 - 550 mg/L. Without ATU) EC50 (3h): 740 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration (650 - 850 mg/L. With ATU)	1 (reliable without restriction) key study experimental study **Test material** Tetraammonium decachloro-µ-oxodiruthenate, Form: solid: particulate/powder **Reference** Muckle M 2015

Discussion

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

The 3h-NOEC for total respiration (without ATU) was 100 mg L^{-1}, 3h-EC10 was 190 mg L^{-1} and 3h-EC50 was 500 mg L^{-1}. The 3h-NOEC for heterotrophic respiration (with ATU) was 180 mg L^{-1}, 3h-EC10 was 250 mg L^{-1} and 3h-EC50 was 640 mg L^{-1}.

Additional information:

Muckle (2015) assessed the inhibition of the respiration of activated sludge when exposed to tetraammonium decachloro-µ-oxodiruthenate. The study is GLP compliant and followed the standard test 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. Three experiments were carried out. In the first experiment, which was performed as the range finding test, the test item was tested at 4 nominal concentrations with and without the nitrification inhibitor N-allylthiourea (ATU). Since significant inhibition was observed, two additional experiments were performed under the same test conditions, but with and without the addition of ATU, respectively. In the test series without ATU, inhibition was slightly higher than in the test series with ATU. This explains that the test item acted as a slight nitrification inhibitor. All validity criteria were met.

The 3h-NOEC for total respiration (without ATU) was 100 mg L^{-1}, 3h-EC10 was 190 mg L^{-1} and 3h-EC50 was 500 mg L^{-1}. The 3h-NOEC for heterotrophic respiration (with ATU) was 180 mg L^{-1}, 3h-EC10 was 250 mg L^{-1} and 3h-EC50 was 640 mg L^{-1}.

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): 0.115 µg/L Intermittent releases: 1.15 µg/L	Assessment factor: 1000 Extrapolation method: assessment factor PNEC aqua (freshwater) The PNEC freshwater is derived based on a lowest EC50 of 0.115 mg Ru L^{-1} and an assessment factor of 1000. For further details see attached PNEC report. The PNEC intermittent releases is derived based on a

		lowest EC50 of 0.115 mg Ru L^{-1} and an assessment factor of 100. For further details see attached PNEC report.
Marine water	PNEC aqua (marine water): 0.011 µg/L	Assessment factor: 10000 Extrapolation method: assessment factor PNEC aqua (marine water) The PNEC marine water is derived based on a lowest EC50 for freshwater species of 0.115 mg Ru L^{-1} and an assessment factor of 10000. For further details see attached PNEC report.
Sediments (freshwater)	PNEC sediment (freshwater): 3.59 mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (freshwater) The PNEC sediment (freshwater) is derived using equilibrium partitioning based on the freshwater PNEC and a Kd value of 31600 L Kg^{-1}. For further details see attached PNEC report.
Sediments (marine water)	PNEC sediment (marine water): 0.359 mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (marine water) The PNEC sediment (marine water) is derived using equilibrium partitioning based on the marine water PNEC and a Kd value of 31600 L Kg^{-1}. For further details see attached PNEC report.
Sewage treatment plant	PNEC STP: 3.03 mg/L	Assessment factor: 10 Extrapolation method: assessment factor PNEC STP The PNEC STP is derived based on a NOEC of 30.3 mg Ru L^{-1} from an activated sludge respiration inhibition test and an assessment factor of 10. For further details see attached PNEC report.
Soil	PNEC soil: 0.729 mg/kg soil dw	Extrapolation method: equilibrium partitioning method PNEC soil The PNEC soil is derived using equilibrium partitioning based on the freshwater PNEC and a Kd value of

		6320 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 be 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

The most sensitive acute result for this substance is an algal EC50 of 0.380 mg test item L^{-1} (growth rate). As this result is <1 mg L^{-1}, an acute environmental classification of Acute category 1 is assigned.

The only available chronic data are an algal NOEC and algal EC10 (0.023 and 0.019 mg test item L^{-1}, respectively). As chronic data are available for only one trophic level, the chronic classification is assessed based on both the acute and chronic data, with the most stringent classification applied. Based on both the acute and chronic data a chronic environmental classification of Chronic category 1 is assigned. Acute and chronic M factors of 1 are also assigned.

General discussion

Klimisch 1 studies are available for acute toxicity to *Daphnia magna*, acute toxicity to fish (*Danio rerio*) and algal growth inhibition (*Pseudokirchneriella subcapitata*) for this substance. All studies report results based on both test item concentrations and measured concentrations of ruthenium. The most sensitive trophic level based on acute data is algae and this result is used in order to determine the environmental classification of the substance. The only available chronic data are an EC10 and NOEC from the same algal study.

For PNEC derivation, data on the substance itself is used but PNEC values are reported based on concentrations of ruthenium. Environmental monitoring of ruthenium does not differentiate between different ruthenium substances therefore reporting PNEC values based on ruthenium concentrations allows the PNEC to be directly compared with predicted environmental concentrations.

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

Assessed composition: Boundary 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

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

9.0.2. Assessment entity groups

Not applicable

9.0.3. Introduction to the assessment for the environment

9.0.3.1. Tonnage

Assessed tonnage: 31.4 tonnes/year as Ru equivalent based on:

- 31.4 tonnes/year manufactured based on Ru equivalent

Table 9.1. Tonnage for assessment

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); with STP (ERC 1) - Manufacture of the substance (as such); direct discharge (ERC 1) - Process in fully contained system (PROC 1) - Closed batch process (PROC 3) - Open or semi-closed reaction process (PROC 4) - Handling and transfer of wetted powders (PROC 26) - Wet cleaning (PROC 8a) - Filling/handling/transfer of solutions (PROC 8b) - Small scale handling/transfer of solutions (PROC 9)	31.4
ES2 – IW1		Use at industrial site - Use as an intermediate - Use as intermediate - industrial with STP (ERC 6a) - Use as intermediate - industrial with direct discharge (ERC 6a) - Closed batch process (PROC 3) - Open or semi-closed reaction process (PROC 4) - Handling and transfer of wetted powders (PROC 26)	31.4

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
		- Wet cleaning (PROC 8a) - Filling/handling/transfer of solutions (PROC 8b) - Small scale handling/transfer of solutions (PROC 9) - Potentially-closed processing at elevated temperature (PROC 22) - Open processing at elevated temperature (PROC 23) - Vacuum cleaning (PROC 26)	
Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)			

9.0.3.2. Scope and type of assessment for the environment

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

Table 9.2. Type of risk characterisation required for the environment

Protection target	Risk characterisation type	Hazard conclusion (see section 7)
Fresh water	Quantitative	PNEC aqua (freshwater) = 0.115 µg/L
Sediment (freshwater)	Quantitative	PNEC sediment (freshwater) = 3.59 mg/kg sediment dw
Marine water	Quantitative	PNEC aqua (marine water) = 0.012 µg/L
Sediment (marine water)	Quantitative	PNEC sediment (marine water) = 0.359 mg/kg sediment dw
Sewage Treatment Plant	Quantitative	PNEC STP = 3.03 mg/L
Air	Not needed	No hazard identified
Agricultural soil	Quantitative	PNEC soil = 0.729 mg/kg soil dw
Predator’s prey (freshwater)	Not needed	No potential to cause toxic effects if accumulated (in higher organisms) via the food chain
Predator’s prey (marine water)	Not needed	No potential to cause toxic effects if accumulated (in higher organisms) via the food chain

Protection target	Risk characterisation type	Hazard conclusion (see section 7)
Top predator's prey (marine water)	Not needed	No potential to cause toxic effects if accumulated (in higher organisms) via the food chain
Predator's prey (terrestrial)	Not needed	No potential to cause toxic effects if accumulated (in higher organisms) via the food chain

9.0.3.3. Fate and distribution parameters

Physicochemical properties used for exposure estimation

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

Table 9.3. Substance key phys-chem and fate properties

Substance property	Value
Molecular weight	
Molecular weight used for the assessment	101.1
Melting point at 101 325 Pa	450 °C
Water solubility	31.1 g/L at 20 °C
Log Kp (solids-water in soil)	3.8 at 20 °C
Log Kp (solids water in sediment)	4.5 at 20 °C
Log Kp (solids-water in suspended matter)	4.5 at 20 °C

Caution: The log Kow is above 5 and the PNEC sediment/soil have been derived on equilibrium partitioning method. Therefore the risk characterisation ratio for sediment/soil will be multiplied by a factor of 10 to account for uncertainty due to the potential for adsorption of the substance.

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

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

Release to water	54%
Release to air	0%
Release to sludge	46%
Release degraded	0%

The fractions reported in the above table have been set by the assessor .

Explanations:

Measured result

9.0.3.4. Comments on assessment approach for the environment

9.0.3.4.1 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 ruthenium (Ru) compounds produced in the EU was sub-divided by region. The value input to modelling was the maximum proportion of Ru compounds produced in a single region. This regional assumption was combined with emission characteristics from the Ru manufacturing and processing sector data (Tables 9.4 and 9.5), STP removal efficiency (Section 9.0.1.1.3) and phys-chem properties to perform calculations of the regional PEC concentrations for freshwater[2] and soil. The estimated regional background PECs were then incorporated into all GESs.

9.0.3.4.2. Local PEC and tiered Risk calculation approach

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

[2] 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))

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

effect concentrations' (PNECs) derived from ecotoxicological testing of tetraammonium decachloro-mu-oxodiruthenate(4-).

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 tetraammonium decachloro-mu-oxodiruthenate(4-) were created. Tier 1 local PEC calculations employed default values from the guidance based on the appropriate Environmental Release Category (ERC). Physico-chemical and fate data discussed in the previous sections of the CSR were used as input values, and the calculated PECs were compared with the PNECs derived in Section 7. If no risks were identified in any compartment or a realistic Msafe tonnage could be calculated, the environmental modelling stopped at this point.

Tier 2

The Tier 1 assessment did not, due to its conservative nature, derive RCR < 1 for most manufacturers or generate representative Msafe tonnage values for downstream user 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 Ru 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 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 Ru compounds as intermediates at the same sites.

9.0.3.4.3 Drafting of ES

For Manufacture and Use as Intermediate at Industrial Sites

Tonnage data were collected from 4 sites and can be considered as representative for the Ru production and processing sector. Due to the limited amount of data on volumes used and the need to protect confidentiality the generic exposure scenario (GES) describing manufacture and use as an intermediate has used the maximum amount for the tonnage band, i.e. 100 tpa.
Ru 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 9.4. This type of information is reported for most of the sites; the median number of emission days the median number of emissions days is 330 d for water and 345 d for air. The lowest of the median values for emission days to water and air (i.e. 330 d/yr) was selected for the GES.

Table 9.4 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 Tetraammonium decachloro-mu-oxodiruthenate(4-))	Emission days per site (d/yr)	
		Water	Air
50P	-	333	365
Min	-	250	360
Max	100 (tonnage band max)[4]	365	365
n	4	4	4
Selected for Exposure Scenario	100 (tonnage band max)[3]	330 (lowest 50P to 2 sig fig)	

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 Ru substances (and their subsequent use as intermediates in further processing) was undertaken using measured emission data collected from the Ru manufacture and processing sector.
Four sites across Europe involved in the production and processing of Ru substances submitted local emission and exposure information. These sites produce and process a number of different Ru 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 Ru originating from the production/use of multiple Ru 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 Ru compounds (although tonnage values and PNECs are specific to individual Ru substances).

Emissions to water

Wastewater containing Ru 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 Ru manufacture and processing sector to derive a release factor (RF) for use in the development of a reasonable worst case (RWC) exposure scenario. A mean or median RF applied to the maximum

[4] Equivalent to 31.4 tpa ruthenium metal

tonnage band value would be considered to give a RWC exposure scenario. However, aquatic emission data were provided by only 3 sites across Europe so the use of adjusted SpERC release factors (RFs) for emissions to the aquatic environment is recommended based on the available data. The release factor to water scenarios is set at 10% of the reported SpERC RF for 'manufacture of metal compounds'[5] (0.04% or 400 g/T as Ru has a Kd of 31600 L/kg). This approach is supported by comparison of the available data to the SpERC RF. The SpERC RF of 0.04% (equivalent to 400 g/T) is almost exactly one order of magnitude higher than the mean measured RF of 42.3 g/T based on quantifiable measurements from three sites manufacturing Ru compounds.
Due to the high monetary value of Ru, emissions are minimised as much as possible leading to lower release factors than for other metals (such as those considered for the basis of the SpERCs). It may therefore be considered reasonable to adjust other metal sector SpERCs for water emissions by up to an order of magnitude when considered high value metals such as ruthenium.

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 Ru manufacturing and processing sector gave information on the flow rates of the ultimate receiving water body, and the STP where relevant. Table 9.5 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 Ru in STPs

For those facilities discharging their wastewater via the sewage system the size of sewage treatment plants (STPs) and their removal efficiency for Ru will also have a significant influence on the PEC in the receiving water body. The removal of Ru 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 Ru processing sites discharging wastewater that had been treated at on-site wastewater treatment plants (WWTPs). Based on measurements of total Ru in influent and effluent, the median removal efficiency for Ru was calculated to be 46% and this value has been used in exposure modelling as the amount of Ru

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

partitioning to sewage sludge at STPs with the remaining 54% 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 Ru-rich particulates. Only a very limited amount of stack emission data were provided, i.e. by only one site manufacturing and processing Ru metal and compounds. The use of SpERC release factors (RFs) from the SpERC document for 'manufacture of metal compounds'[7] is recommended in the absence of representative sector data. The SpERC RF for air of 0.3% (equivalent to 300 g/T) is used to develop the GES for sites manufacturing Ru compounds.

Table 9.5: Release factor and dilution capacity for discharge to aquatic environment during manufacture of Ru compounds and their use as intermediates at industrial sites (ES 1.1, 1.2, 2.1 and 2.2)

Value	Release factor (RF) (g/T)	On-site effluent flow (m^3/d)	STP flow (m^3/d)	River flow rate (m^3/d)	Dilution factor to STP	Dilution factor STP to river
Median (50P)	-	120	35000	6972480	78	46.7
90P	-			16000000		
10P	-		9360	51083.4		
Min	-	60	2950	2950	25	1
Max	-	450	1344000	16000000	22818	458
N	3	3	3	2	3	2
Selected for ES 1.1 & 2.1 Freshwater – via STP	40 (10% SpERC)	120 (50P)	9360 (10P STP flow rate)		78 (based on median effluent flow rate & 10P STP flow)	50 (nominal dilution factor based on PGM

[6] Stutt E, Wilson I, Merrington G & Rothenbacher K (2016) Determining the Removal of Ruthenium 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
						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)		

The regional concentrations are reported in section 10.2.1.1. The local Predicted Exposure Concentrations (PECs) reported for each contributing scenario correspond to the sum of the local concentrations (Clocal) and the regional concentrations (PEC regional).

9.0.3.5. Scope and type of assessment for 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].

9.0.3.6. 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 9.6. Type of risk characterisation required for workers

[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 (2016) 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 (see section 5.11)
Inhalation	Systemic, long-term	Quantitative	DNEL (Derived No Effect Level) = 0.28 mg/m³
	Systemic, acute	Not needed	No hazard identified
	Local, long-term	Qualitative	Medium hazard (no threshold derived)
	Local, acute	Qualitative	Medium hazard (no threshold derived)
Dermal	Systemic, long-term	Quantitative	DNEL (Derived No Effect Level) = 0.4 mg/kg bw/day
	Systemic, acute	Not needed	No hazard identified
	Local, long-term	Qualitative	Medium hazard (no threshold derived)
	Local, acute	Qualitative	Medium hazard (no threshold derived)
Eye	Local	Qualitative	Medium hazard (no threshold derived)

Comments on assessment approach related to toxicological hazard:

GENERAL GOOD OCCUPATIONAL HYGIENE PRACTICES

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

(i) contaminated clothing is not taken home,

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

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

QUALITATIVE RISK CHARACTERISATION FOR LOCAL EFFECTS

In addition to the quantitative risk characterisation, demonstrating that prescribed operational conditions and risk management measures effectively control exposure below the respective DNELs, residual exposure concentrations may theoretically still cause local effects. As a precautionary measure, it is therefore prescribed to use personal protective equipment (e.g. gloves, face protection, goggles/visors, and/or respiratory protective equipment; see further details below) in situations in which such residual exposure concentrations cannot be excluded. The risk of local effects is therefore also considered to be adequately controlled.

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

General information on risk management related to toxicological hazard:

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

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

INHALATION ROUTE (RESPIRATORY PROTECTION)
When respiratory protective equipment (RPE) is required, specific information on the required assigned protection factor (APF) is provided in the occupational exposure scenarios below. RPE should be selected based on the given APF according to EN 529 and should comply with national legislation. If RPE has to be worn, an APF of 10 represents the required minimum level of protection. RPE shall only be worn if the following principles are implemented in parallel: The duration of work should take into account the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself and due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore:
(i) be healthy (especially in view of medical problems that may affect the use of RPE), and
(ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair).
The devices recommended in the ES which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

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

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

9.0.3.7. Consumers

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

9.0.3.8 Physico-chemical properties

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 2 (Hazard assessment for physico-chemical properties) no hazard was identified. Consequently, all identified uses of the substance are assessed as safe related to the physico-chemical properties.

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

Environment contributing scenario(s):		
CS 1	Manufacture (of the substance as such); with STP	ERC 1
CS 2	Manufacture (of the substance as such); Direct discharge	ERC 1
Worker contributing scenario(s):		
CS 3	Process in fully contained system	PROC 1
CS 4	Closed batch process	PROC 3
CS 5	Open or semi-closed reaction process	PROC 4
CS 6	Wet cleaning	PROC 8a
CS 7	Filling/handling/transfer of solutions	PROC 8b
CS 8	Small scale handling/transfer of solutions	PROC 9

Explanation on the approach taken for the ES

9.1.1. Env CS 1: Manufacture (of the substance as such); with STP (ERC 1)

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 0.095 tonnes/day *Based on company data of 330 days release to water per annum* • Annual use amount at site: <= 31.4 tonnes/year
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 46%] • Discharge rate of STP: >= 9360 m3/day *10th percentile of company data* • Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
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. Releas-es to the floor, water and soil are to be prevented. If the ruthenium 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 08 03, 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 ruthenium is recycled for almost a 100% A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 458640 m3/day

Fate (release percentage) in the biological sewage treatment plant

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

Release to water	54%
Release to air	0%
Release to sludge	46%
Release degraded	0%

Explanations :

Measured result

9.1.1.2. Releases

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

Table 9.7. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor (10 % of SpERC)	**Release factor before on site RMM:** 4E-3% **Release factor after on site RMM:** 4E-3% **Local release rate:** 3.8E-3 kg/day
Air	Estimated release factor (SpERC)	**Release factor before on site RMM:** 0.03% **Release factor after on site RMM:** 0.03% **Local release rate:** 0.029 kg/day
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:**

Release	Release estimation method	Explanations
		Industrial best practice

9.1.1.3. Exposure and risks for the environment

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

Table 9.7. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 2.98E-6 mg/L	RCR = 0.026
Sediment (freshwater)	**Local PEC:** 0.094 mg/kg dw	RCR = 0.262
Sewage Treatment Plant	**Local PEC:** 2.19E-4 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 9.39E-5 mg/kg dw	RCR < 0.01

9.1.2. Env CS 2: Manufacture (of the substance as such); Direct discharge (ERC 1)

9.1.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 0.095 tonnes/day *Based on company data of 330 days release to water per annum* • Annual use amount at site: <= 31.4 tonnes/year
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
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. Releas-es to the floor, water and soil are to be prevented. If the ruthenium 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 08 03, 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 ruthenium is recycled for almost a 100% A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 2997000 m3/day • Discharge rate of effluent: >= 3000 m3/day

9.1.2.2. Releases

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

Table 9.8. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor (10 % of SpERC)	**Release factor before on site RMM:** 4E-3% **Release factor after on site RMM:** 4E-3% **Local release rate:** 3.8E-3 kg/day
Air	Estimated release factor (SpERC)	**Release factor before on site RMM:** 0.03% **Release factor after on site RMM:** 0.03% **Local release rate:** 0.029 kg/day
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** Industrial best practice

9.1.2.3. Exposure and risks for the environment

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

Table 9.9. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 8.62E-7 mg/L	RCR < 0.01
Sediment (freshwater)	**Local PEC:** 0.027 mg/kg dw	RCR = 0.076
Sewage Treatment Plant	**Local PEC:** 0 mg/L	RCR < 0.01

Protection target	Exposure concentration	Risk quantification
Agricultural soil	**Local PEC:** 9.39E-5 mg/kg dw	RCR < 0.01

9.1.3 Worker contributing scenario 1: Process in fully contained system (PROC 1)

9.1.3.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	External Tool (MEASE)
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Maximum process temperature: 70 °C	External Tool (MEASE)
• Level of containment: Closed process	External Tool (MEASE)
• Pattern of use: Closed system without breaches	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: None	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the	

	Method
substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.1.3.2. Exposure and risks for workers

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

Table 9.10. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.01 mg/m³** (External Tool (MEASE))	RCR = 0.036
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.17 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.036

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.1.4. Worker contributing scenario 2: Closed batch process (PROC 3)

9.1.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	External Tool (MEASE)
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Level of containment: Closed process	External Tool (MEASE)
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)
• Generic local exhaust ventilation: Lower confidence limit (industrial use) (Standard efficiency) [Effectiveness Inhal: 78%]	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is	External Tool (MEASE)

	Method
required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.1.3.2. Exposure and risks for workers

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

Table 9.11. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.22 mg/m³** (External Tool (MEASE))	RCR = 0.786
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.17 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.786

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.1.5. Worker contributing scenario 3: Open or semi-closed reaction process (PROC 4)

9.1.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	External Tool (MEASE)
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) (Standard efficiency) [Effectiveness Inhal: 84%]	External Tool (MEASE)
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) must be worn: RPE (minimum assigned protection factor of 20) is prescribed for all workplaces unless inhalation exposure to the substance can be excluded.	External Tool (MEASE)
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	

9.1.5.2. Exposure and risks for workers

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

Table 9.12. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.2 mg/m³** (External Tool (MEASE))	RCR = 0.714
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.34 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.715

Remarks on exposure data

External Tool (MEASE)

- Dermal, systemic, long-term:

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs<1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.1.6. Worker contributing scenario 4: Handling and transfer of wetted powders (PROC 26)

9.1.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, damp powder	External Tool (MEASE)
• Maximum emission potential of the substance: Low (powder kept wetted to reduce dustiness)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) (Standard efficiency) [Effectiveness Inhal: 84%]	External Tool (MEASE)
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Extensive	External Tool (MEASE)

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	

9.1.6.2. Exposure and risks for workers

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

Table 9.13. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.24 mg/m³** (External Tool (MEASE))	RCR = 0.857
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.4 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Combined routes, systemic, long-term		RCR = 0.861

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.1.7. Worker contributing scenario 5: Wet cleaning (PROC 8a)

9.1.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution, suspension	External Tool (MEASE)
• Maximum emission potential of the substance: Very low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	

	Method
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Direct handling	External Tool (MEASE)
• Contact level: Extensive	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.1.7.2. Exposure and risks for workers

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

Table 9.14. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.05 mg/m³** (External Tool (MEASE))	RCR = 0.179
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**34 µg/kg bw/day** (External Tool (MEASE))	RCR = 0.085

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.264

Remarks on exposure data

External Tool (MEASE)

- Dermal, systemic, long-term:

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.1.8. Worker contributing scenario 6: Filling/handling/transfer of solutions (PROC 8b)

9.1.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	External Tool (MEASE)
• Maximum emission potential of the substance: Very low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
Amount used (or contained in articles), frequency and duration of use/exposure	

	Method
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.1.8.2. Exposure and risks for workers

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

Table 9.15. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.01 mg/m³** (External Tool (MEASE))	RCR = 0.036
Inhalation, local, long-term		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.34 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.037

Remarks on exposure data

External Tool (MEASE)

- Dermal, systemic, long-term:

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.1.9. Worker contributing scenario 7: Small scale handling/transfer of solutions (PROC 9)

9.1.9.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	External Tool (MEASE)
• Maximum emission potential of the substance: Very low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower	External Tool (MEASE)

	Method
dustiness are being handled in parallel) are thus automatically covered in this assessment.)	
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.1.9.2. Exposure and risks for workers

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

Table 9.16. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.01 mg/m³** (External Tool (MEASE))	RCR = 0.036
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**3.4 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.044

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

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

Sector of use: SU 14: Manufacture of basic metals, including alloys; SU 24: Scientific research and development; SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals

Environment contributing scenario(s):	
Use as intermediate - industrial with STP	ERC 6a
Use as intermediate - industrial with direct discharge	ERC 6a
Worker contributing scenario(s):	
Closed batch process	PROC 3
Open or semi-closed reaction process	PROC 4
Wet cleaning	PROC 8a
Filling/handling/transfer of solutions	PROC 8b
Small scale handling/transfer of solutions	PROC 9
Potentially-closed processing at elevated temperature	PROC 22
Open processing at elevated temperature	PROC 23
Vacuum cleaning	PROC 26

Explanation on the approach taken for the ES

9.2.1. Env CS 1: Use as an intermediate - industrial; with STP (ERC 6a)

9.2.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 0.095 tonnes/day • Annual use amount at site: <= 31.4 tonnes/year
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 46%] • Discharge rate of STP: >= 9360 m3/day • Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
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. Releas-es to the floor, water

and soil are to be prevented. If the ruthenium 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 08 03, 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 ruthenium is recycled for almost a 100% A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 458640 m3/day

Fate (release percentage) in the biological sewage treatment plant

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

Release to water	54%
Release to air	0%
Release to sludge	46%
Release degraded	0%

Explanations :

Measured result

9.2.1.2. Releases

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

Table 9.17. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 4E-3% **Release factor after on site RMM:** 4E-3% **Local release rate:** 3.8E-3 kg/day
Air	Estimated release factor	**Release factor before on site RMM:** 0.03% **Release factor after on site RMM:** 0.03% **Local release rate:** 0.029 kg/day

Release	Release estimation method	Explanations
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0%

9.2.1.3. Exposure and risks for the environment

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

Table 9.18. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 2.98E-6 mg/L	RCR = 0.026
Sediment (freshwater)	**Local PEC:** 0.094 mg/kg dw	RCR = 0.262
Sewage Treatment Plant	**Local PEC:** 2.19E-4 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 9.39E-5 mg/kg dw	RCR < 0.01

9.2.2. Env CS 2: Use as an intermediate - industrial; Direct Discharge (ERC 6a)

9.2.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 0.095 tonnes/day • Annual use amount at site: <= 31.4 tonnes/year
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
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. Releas-es to the floor, water and soil are to be prevented. If the ruthenium 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 08 03, 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 ruthenium is recycled for almost a 100% A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 2997000 m3/day • Discharge rate of effluent: >= 3000 m3/day

9.2.2.2. Releases

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

Table 9.19. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 4E-3% **Release factor after on site RMM:** 4E-3% **Local release rate:** 3.8E-3 kg/day
Air	Estimated release factor	**Release factor before on site RMM:** 0.03% **Release factor after on site RMM:** 0.03% **Local release rate:** 0.029 kg/day
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0%

9.2.2.3. Exposure and risks for the environment

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

Table 9.20. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 8.62E-7 mg/L	RCR < 0.01
Sediment (freshwater)	**Local PEC:** 0.027 mg/kg dw	RCR = 0.076

Protection target	Exposure concentration	Risk quantification
Sewage Treatment Plant	**Local PEC:** 0 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 9.39E-5 mg/kg dw	RCR < 0.01

9.2.3. Worker contributing scenario 1: Closed batch process (PROC 3)

9.2.3.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	External Tool (MEASE)
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Level of containment: Closed process	External Tool (MEASE)
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)
• Generic local exhaust ventilation: Lower confidence limit (industrial use) (Standard efficiency) [Effectiveness Inhal: 78%]	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the	

	Method
substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.2.3.2. Exposure and risks for workers

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

Table 9.21. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.22 mg/m³** (External Tool (MEASE))	RCR = 0.786
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.17 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.786

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.2.4. Worker contributing scenario 2: Open or semi-closed reaction process (PROC 4)

9.2.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	External Tool (MEASE)
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) (Standard efficiency) [Effectiveness Inhal: 84%]	External Tool (MEASE)
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE) must be worn: RPE (minimum assigned protection factor of 20) is prescribed for all workplaces unless inhalation exposure to the substance can be excluded.	External Tool (MEASE)
• Gloves/face protection: Due to the potential adverse effects of the	External Tool (MEASE)

	Method
substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	

9.2.4.2. Exposure and risks for workers

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

Table 9.22. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.2 mg/m³** (External Tool (MEASE))	RCR = 0.714
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.34 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.715

Remarks on exposure data

External Tool (MEASE)

- Dermal, systemic, long-term:
  For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained

in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.2.5. Worker contributing scenario 3: Handling and transfer of wetted powders (PROC 26)

9.2.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, damp powder	External Tool (MEASE)
• Maximum emission potential of the substance: Low (powder kept wetted to reduce dustiness)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) (Standard efficiency) [Effectiveness Inhal: 84%]	External Tool (MEASE)
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Extensive	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier.	External Tool (MEASE)

	Method
[Effectiveness Dermal: 90%]	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	

9.2.5.2. Exposure and risks for workers

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

Table 9.23. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.24 mg/m³** (External Tool (MEASE))	RCR = 0.857
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.4 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.861

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.2.6. Worker contributing scenario 4: Wet cleaning (PROC 8a)

9.2.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution, suspension	External Tool (MEASE)
• Maximum emission potential of the substance: Very low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Direct handling	External Tool (MEASE)
• Contact level: Extensive	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is	External Tool (MEASE)

	Method
required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.2.6.2. Exposure and risks for workers

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

Table 9.24. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.05 mg/m³** (External Tool (MEASE))	RCR = 0.179
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**34 µg/kg bw/day** (External Tool (MEASE))	RCR = 0.085
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.264

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

Under the prescribed conditions of use, estimated exposures are below the respective DNELs and, therefore, risks are considered to be adequately controlled.

9.2.7. Worker contributing scenario 5: Filling/handling/transfer of solutions (PROC 8b)

9.2.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	External Tool (MEASE)
• Maximum emission potential of the substance: Very low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is	External Tool (MEASE)

	Method
required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.2.7.2. Exposure and risks for workers

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

Table 9.25. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.01 mg/m³** (External Tool (MEASE))	RCR = 0.036
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.34 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.037

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.2.8. Worker contributing scenario 6: Small scale handling/transfer of solutions (PROC 9)

9.2.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	External Tool (MEASE)
• Maximum emission potential of the substance: Very low (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the	External Tool (MEASE)

	Method
substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.2.8.2. Exposure and risks for workers

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

Table 9.26. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.01 mg/m³** (External Tool (MEASE))	RCR = 0.026
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**3.4 µg/kg bw/day** (External Tool (MEASE))	RCR = 0.013
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.039

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.2.9. Worker contributing scenario 7: Potentially-closed processing at elevated temperature (PROC 22)

9.2.9.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	External Tool (MEASE)
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.)	External Tool (MEASE)
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Process temperature: Elevated, but below melting point (i.e. < 450 °C)	External Tool (MEASE)
• Generic local exhaust ventilation: Lower confidence limit (industrial use) (Standard efficiency) [Effectiveness Inhal: 78%]	External Tool (MEASE)
• Pattern of use: Non-dispersive use	External Tool (MEASE)

	Method
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.2.9.2. Exposure and risks for workers

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

Table 9.27. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.22 mg/m³** (External Tool (MEASE))	RCR = 0.786
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.4 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.789

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.2.10. Worker contributing scenario 8: Open processing at elevated temperature (PROC 23)

9.2.10.1. Conditions of use

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

	Method
Inhal: 0%; Dermal: 0%]	
Technical and organisational conditions and measures	
• Process temperature: Elevated, but below melting point (i.e. < 450 °C)	External Tool (MEASE)
• Generic local exhaust ventilation: Lower confidence limit (industrial use) (Standard efficiency) [Effectiveness Inhal: 78%]	External Tool (MEASE)
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Intermittent	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation (moderate hazard). (Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.)	

9.2.10.2. Exposure and risks for workers

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

Table 9.28. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.11 mg/m³** (External Tool (MEASE))	RCR = 0.393
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.4 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.396

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

9.2.11. Worker contributing scenario 9: Vacuum cleaning (PROC 26)

9.2.11.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	External Tool (MEASE)
• Maximum emission potential of the substance: High (Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower	External Tool (MEASE)

	Method
dustiness are being handled in parallel) are thus automatically covered in this assessment.)	
• Content in preparation: Not restricted [Effectiveness Inhal: 0%; Dermal: 0%]	External Tool (MEASE)
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%]	External Tool (MEASE)
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) (Standard efficiency) [Effectiveness Inhal: 84%] *Surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner.*	External Tool (MEASE)
• Pattern of use: Non-dispersive use	External Tool (MEASE)
• Pattern of exposure control: Non-direct handling	External Tool (MEASE)
• Contact level: Extensive	External Tool (MEASE)
• Additional operational conditions for cleaning: No direct manual removal of dust.	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 (APF = assigned protection factor according to EN 529. At minimum any combination of particle filter class P3 with mask according to EN 140, EN 1827 or filtering half mask (FF P3) according to EN 149 or combination of P2 filter with face piece according to EN 12941 or EN 12942 or any RPE providing higher APFs according to EN 529 is required.) [Effectiveness Inhal: 95%]	External Tool (MEASE)
• Gloves/face protection: Due to the potential adverse effects of the substance to skin (moderate hazard), protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]	External Tool (MEASE)
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes (moderate hazard). (Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated	

	Method
surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.)	

9.2.11.2. Exposure and risks for workers

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

Table 9.29. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.08 mg/m³** (External Tool (MEASE))	RCR = 0.286
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.4 µg/kg bw/day** (External Tool (MEASE))	RCR < 0.01
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.289

Remarks on exposure data

External Tool (MEASE)

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

Conclusion on risk characterisation

Under the prescribed conditions of use, quantitative estimated exposures are below the respective DNELs (RCRs < 1).

Further information on the risk characterisation for local effects via inhalation, for local dermal effects and local effects to the eyes is given in Section 9.0.2.3.

On this basis, systemic and local risks are considered to be adequately controlled.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

This chapter describes why a separate risk characterisation related to combined exposure is not required. Combined exposure may result from any of the following scenarios:

1. Multiple ruthenium substances handled in parallel at the same workplace,
2. Inhalation and dermal exposure route contributing to systemic effects at the same time,
3. More than just a single contributing occupational exposure scenario relevant for an individual worker,
4. Workers that are also exposed to ruthenium substances in their free time

These scenarios are considered below:

1. Multiple ruthenium substances handled in parallel at the same workplace
Exposure monitoring data were obtained from a number of workplaces where ruthenium and/or ruthenium substances are manufactured or used in parallel. Any samples are analysed for their ruthenium content rather than for the content of the respective ruthenium substance. Thus, measured ruthenium levels are intrinsically reflective of any potential parallel exposure to multiple ruthenium substances and are not only relevant for a single ruthenium substance. An exposure assessment based on such monitoring data can therefore be considered to include an assessment for any ruthenium substance handled in parallel. For assessments based on modelling tools, it is noted that the handled amount is not considered as an input parameter. For small-scale activities as relevant in the ruthenium industry, it can be assumed that these are covered for all substances handled in parallel by the exposure estimates, which refer to large scale and highly industrialised workplaces.

2. Inhalation and dermal exposure route contributing to systemic effects at the same time
A combined RCR is always maintained significantly below 1 in each of the ES.

3. More than just a single contributing occupational exposure scenario relevant for an individual worker
For aggregated exposure resulting from the applicability of more than just a single contributing worker scenario in a single work shift, it is noted that all exposure levels were derived for a full-shift exposure time and a safe use was demonstrated for each contributing scenario. Thus, by demonstrating safe

use for individual contributing scenarios it is assured that a combination of activities within a single shift, could not exceed the highest calculated RCR for any of the individual activities in that shift.

4. Workers that are also exposed to ruthenium substances in their free time (e.g. as member of the general population or as consumer)
For workers who are members of other populations to be protected in this chemical safety assessment (i.e. general population), a specific combined exposure assessment is not required as workers represent a less vulnerable population in comparison to subpopulations (e.g. children) which may be considered in assessments for the general population. Any RCR from these subpopulations could safely be assumed to be in fact significantly lower if re-calculated for workers. In a combined assessment of exposures one would also avoid adding the worst case RCR for workers with the worst case RCR of another population as this would lead to an unrealistic scenario. Instead typical RCRs would be taken which would in combination lead to a low combined RCR. In any case, ruthenium substances are not widely dispersed, and the general population is highly unlikely to ever be exposed.

10.1.2. Consumer

Not relevant.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

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

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

Release route	Total releases per year
Water	2.512 kg/year
Air	18.84 kg/year
Soil	0 kg/year

10.2.2. Regional assessment

The regional predicted environmental concentration (PEC regional) and the related risk

characterisation ratios when a PNEC are presented in the table below. The exposure concentration via inhalation is equal to the PEC air.

The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

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

Protection target	Regional PEC	Risk characterisation
Fresh water	**Regional PEC:** 2.71E-9 mg/L	RCR < 0.01
Sediment (freshwater)	**Regional PEC:** 1.72E-4 mg/kg dw	RCR < 0.01
Marine water	**Regional PEC:** 4.04E-10 mg/L	RCR < 0.01
Sediment (marine water)	**Regional PEC:** 2.56E-5 mg/kg dw	RCR < 0.01
Agricultural soil	**Regional PEC:** 8.65E-7 mg/kg dw	RCR < 0.01

10.2.3. Local exposure due to all widespread uses

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

10.2.4. Local exposure due to combined uses at a site

Not relevant

Annexes

1. Annex: References

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