



CHEMICAL SAFETY REPORT

Substance Name: [Ruthenium trichloride hydrate](#)

EC Number: 604-667-4

CAS Number:

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: CSR (all uses)



2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

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

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



3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

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

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



Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

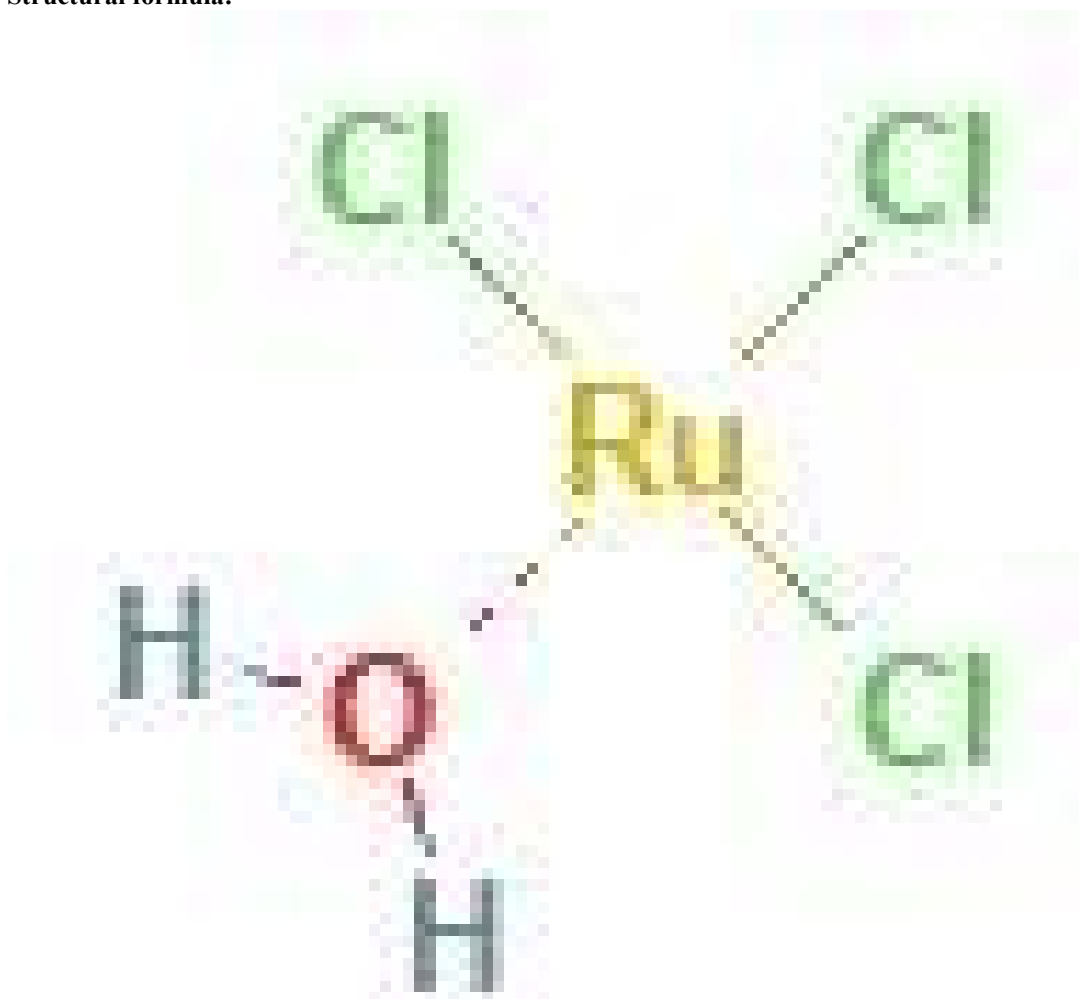
The substance [Ruthenium trichloride hydrate](#) is a mono-constituent substance (inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

The following public name is used:

Table 1.1. Substance identity

EC number:	604-667-4
EC name:	
CAS number (EC inventory):	
CAS number:	14898-67-0
IUPAC name:	Ruthenium trichloride hydrate
Molecular formula:	$\text{RuCl}_3 \cdot x\text{H}_2\text{O}$
Molecular weight range:	$\geq 225.44 - \leq 261.48$

Structural formula:





1.2. Composition of the substance

Overall information on composition:

Composition	Related composition(s)
Ruthenium trichloride (hydrate) (Legal entity composition) (legal entity composition of the substance)	
Ruthenium trichloride (hydrate) (Boundary composition) (boundary composition of the substance)	

Name: Ruthenium trichloride (hydrate) (Legal entity composition)

(legal entity composition of the substance)

State/form: solid: particulate/powder

Degree of purity: % (w/w)

Table 1.2. Constituents (Ruthenium trichloride (hydrate) (Legal entity composition))

Constituent	Typical concentration	Concentration range	Remarks
Ruthenium trichloride hydrate EC no.: 604-667-4	% (w/w)	% (w/w)	

Table 1.3. Impurities (Ruthenium trichloride (hydrate) (Legal entity composition))

Constituent	Typical concentration	Concentration range	Remarks
Hydrogen Chloride EC no.: 231-595-7	% (w/w)	% (w/w)	
Impurities EC no.:	% (w/w)	% (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

Name: Ruthenium trichloride (hydrate) (Boundary composition)

(boundary composition of the substance)

State/form: solid: particulate/powder

Degree of purity: ≥ 89 - ≤ 100 % (w/w)

Description: Under REACH, it is generally recognized that the anhydrous and hydrated forms of a substance are in most cases regarded as the same substance (despite potentially having different CAS numbers). As such, they are mostly covered by the same REACH dossier. However, experts of the PMC concluded during substance ID discussions that Ruthenium trichloride is an exception to this rule: Ruthenium trichloride (hydrate) is not the same substance as Ruthenium trichloride (anhydrous). The 'hydration water' in Ruthenium trichloride (hydrate) is not bound via hydrogen bonds to the metal ion, as is the case in 'common' hydrates, but is coordinated to the metal to form water soluble chloro-aqua complexes. The anhydrous forms are very low solubility chloro-bridged polymers/oligomers. Because of this different chemical structure of the hydrated vs anhydrous form, the substance properties differ and both forms need registration in different REACH dossiers.



Table 1.4. Constituents (Ruthenium trichloride (hydrate) (Boundary composition))

Constituent	Typical concentration	Concentration range	Remarks
Ruthenium trichloride hydrate EC no.: 604-667-4	96 % (w/w)	≥ 89 - ≤ 100 % (w/w)	

Table 1.5. Impurities (Ruthenium trichloride (hydrate) (Boundary composition))

Constituent	Typical concentration	Concentration range	Remarks
Hydrogen Chloride EC no.: 231-595-7	3.3 % (w/w)	≥ 0 - ≤ 10 % (w/w)	
Impurities EC no.:	< 0.7 % (w/w)	≥ 0 - ≤ 1 % (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	Value used for CSA / Discussion	Description of key information
Physical state	solid at 20°C and 101.3 kPa A statement on the appearance of the substance is taken from the test material section of a GLP-compliant study on physico-chemical properties of the substance (Walker and White 2011). It is considered adequate for assessment of this endpoint. Ruthenium trichloride (hydrated solid) is a black powder.	Ruthenium trichloride (hydrated solid) is a black powder.
Melting / freezing point	450°C at 101.3 kPa Walker and White (2011) is a GLP compliant study following OECD guideline 102 and EU method A1. It is considered suitable for use as the key study for this endpoint. Ruthenium trichloride decomposed from approximately 90°C with no definitive signs of melting below 450°C.	Ruthenium trichloride decomposed from approximately 90°C with no definitive signs of melting below 450°C.
Relative density	2.9 at 20°C The raw density of ruthenium trichloride (hydrate) was determined following the	The average raw density of ruthenium trichloride (hydrate) was determined to be 2.90 g/cm ³ .



	guideline DIN 66137 -2:2004 -12, a pycnometer method (Potthoff 2015). The study is suitable for use as the key study for this endpoint. The average raw density of ruthenium trichloride (hydrate) was determined to be 2.90 g/cm ³ .	
Granulometry	Walker and White (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 ruthenium trichloride (hydrate) < 100 µm is 56.7%.	The proportion of ruthenium trichloride (hydrate) <100 µm was 56.7%.
Vapour pressure	0Pa at 20°C Ruthenium trichloride is an inorganic non volatile substance. A very low value has been included for the exposure assessment.	
Water solubility	1140g/L at Gregory (2014) followed a standard shake flask method and is reported in a published article. The water solubility of ruthenium (III) chloride hydrate was reported as 1140 g/L at 20°C.	The water solubility of ruthenium (III) chloride hydrate was reported as 1140 g/L at 20°C.
Autoflammability / self-ignition temperature	Walker and White (2011) is a GLP compliant study following a modified UN N4 method and is considered suitable for use as the key study for this endpoint. Ruthenium trichloride (hydrate) showed no signs of self-ignition or self-heating over the duration of the test.	Ruthenium trichloride (hydrate) showed no signs of self-ignition or self-heating over the duration of the test.
Flammability	not classified Walker and White (2011) is a GLP compliant study following UN method N1 and is considered suitable for use as the key study for this endpoint. Ruthenium trichloride (hydrate) is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.	Ruthenium trichloride (hydrate) is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.
Oxidising properties	non oxidising	Based on read across from rhodium



	The oxidising properties of ruthenium trichloride are read across from another substance with a halogen ligand or counter ion in the 3+ oxidation state (rhodium triiodide). This substance is not oxidising based on GLP-compliant, guideline experimental study (Atwal and Tremain 2011). There is also supplementary evidence that other metal chlorides are also not oxidizing. For example, other Group VIII transition metals such as cobalt (II) chloride, iron (II), iron(III) and nickel(II) chloride. Copper(I) chloride from the adjacent Group IB is also not classified for oxidizing properties. There is therefore no evidence that any transition metal chloride is an oxidant. Supplementary evidence also comes from the non-transition metal chlorides and there is no evidence from two centuries of industrial and academic experience that these substances are oxidants. On the basis of read-across ruthenium trichloride is not classified as an oxidising solid.	triiodide, ruthenium trichloride is not considered to be oxidising.
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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]



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 extreme low pH, ruthenium trichloride is classified as Metal corrosivity category 1 (H290).



2. MANUFACTURE AND USES

2.1. Manufacture

Table 2.1. Manufacture

	Manufacture
M-1	Manufacture (of the substance as such) <u>Further description of manufacturing process:</u> Mixtures of impure RuCl₃ Hydrate, and Ruthenates from recycling process are oxidized to Ruthenium tetroxide, which evaporates in gaseous form, due to bad solubility in aqueous solution. The distillate is absorbed in aqueous hydrochloric acid, where aquation and hydrolisation occurs. Resulting solution of RuCl₃ Hydrat is carefully evaporated to requested concentration or to the solid. Contributing activity/technique for the environment : - Manufacture (of the substance as such) - Discharge via STP (ERC1) - Manufacture (of the substance as such) - Direct discharge (ERC1) Contributing activity/technique for the workers : - Process in fully contained system (PROC 1) (PROC 1) - Closed batch process (PROC 3) (PROC 3) - Open or semi-closed reaction process (PROC 4) (PROC 4) - Transfer of substance (charging/discharging) at non-dedicated facilities (PROC 8a) (PROC 8a) - Transfer of substance (charging/discharging) at non-dedicated facilities (PROC 8a) (PROC 8b) - Wet cleaning (PROC 8a) (PROC 8a) - Handling of solid inorganic substances at ambient temperature (PROC 26) (PROC 26) - Filling/handling/transfer of solutions (PROC 8b) (PROC 8b) - Transfer of substance into small containers (including weighing) (PROC 9) (PROC 9) - Small scale handling/transfer of solutions (PROC 9) (PROC 9) - Use as laboratory reagent (PROC 15) (PROC 15) - Laboratory analyses (PROC 15) (PROC 15) - Open processing at elevated temperature (PROC 23) (PROC 23) - Vacuum cleaning (PROC 26) (PROC 26) use registered according to REACH Article 10; total tonnage manufactured/imported ≥10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Related assessment: use assessed in an own CSR
M-2	Manufacture of the substance in the catalyst industry <u>Further description of manufacturing process:</u> Contributing activity/technique for the environment : - Manufacture of the substance in the catalyst industry (ERC1) Contributing activity/technique for the workers : - Fully contained process (PROC 1) (PROC 1) - Closed batch process (PROC 3) (PROC 3) - Filling/handling/transfer of solutions (PROC 8b) (PROC 8b) - Small scale handling/transfer of solutions (PROC 9) (PROC 9) - Potentially-closed processing at elevated temperature (PROC 22) (PROC 22) - Vacuum cleaning (PROC 26) (PROC 26) - Production of metal powders (wet processes) (PROC 27b) (PROC 27b) use registered according to REACH Article 10; total tonnage manufactured/imported ≥10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Related assessment: use assessed in an own CSR



2.2. Identified uses

Table 2.2. Formulation

	Formulation
F-1	Formulation of surface treatment solutions <u>Further description of the use:</u> Contributing activity/technique for the environment : - Formulation of surface treatment solutions (ERC2) Contributing activity/technique for the workers : - Closed batch process (PROC 3) (PROC 3) - Open or semi-closed reaction process (PROC 4) (PROC 4) - Small scale handling/transfer of solutions (PROC 9) (PROC 9) - Vacuum cleaning (PROC 26) (PROC 26) - Production of metal powders (wet processes) (PROC 27b) (PROC 27b) Product Category formulated: PC 14: Metal surface treatment products Technical function of the substance: plating agents and metal surface treating agents use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Substance supplied to that use: Related assessment: use assessed in an own CSR

Table 2.3. Uses at industrial sites

	Uses at industrial sites
IW-1	Use in electroplating - Industrial <u>Further description of the use:</u> Contributing activity/technique for the environment : - Use in electroplating - Industrial (ERC5) Contributing activity/technique for the workers : - Closed continuous process with occasional controlled exposure (PROC 2) (PROC 2) - Open or semi-closed reaction process (PROC 4) (PROC 4) - Filling/handling/transfer of solutions (PROC 8b) (PROC 8b) - Small scale handling/transfer of solutions/suspensions (PROC 9) (PROC 9) - Treatment of articles by dipping and pouring (PROC 13) (PROC 13) - Hand mixing (PROC 19) (PROC 19) Product Category used: PC 14: Metal surface treatment products Technical function of the substance: plating agents and metal surface treating agents use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Substance supplied to that use: Subsequent service life relevant for that use: yes Link to the subsequent service life: Service life of treated articles Related assessment: use assessed in an own CSR
IW-2	Use as intermediate - industrial <u>Further description of the use:</u> Contributing activity/technique for the environment : - Use as intermediate - industrial with STP (ERC6a) - Use as intermediate - industrial with direct discharge (ERC6a) Contributing activity/technique for the workers : - Process in fully contained system (PROC 1) (PROC 1) - Closed batch process (PROC 3) (PROC 3)



	- Open or semi-closed reaction process (PROC 4) (PROC 4) - Mixing or blending in batch process (PROC 5) (PROC 5) - Transfer of substance (charging/discharging) at non-dedicated facilities (PROC 8a) (PROC 8a) - Transfer of substance (charging/discharging) at dedicated facilities (PROC 8b) (PROC 8b) - Wet cleaning (PROC 8a) (PROC 8a) - Handling of solid inorganic substances at ambient temperature (PROC 26) (PROC 26) - Filling/handling/transfer of solutions (PROC 8b) (PROC 8b) - Transfer of substance into small containers (including weighing) (PROC 9) (PROC 9) - Small scale handling/transfer of solutions (PROC 9) (PROC 9) - Use as laboratory reagent (PROC 15) (PROC 15) - Laboratory analyses (PROC 15) (PROC 15) - Vacuum cleaning (PROC 26) (PROC 26) Sector of end use: SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) ; SU 9: Manufacture of fine chemicals ; SU 24: Scientific research and development Technical function of the substance: intermediate (precursor) use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Substance supplied to that use: Subsequent service life relevant for that use: no Related assessment: use assessed in an own CSR
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Table 2.4. Uses by professional workers

	Uses by professional workers
PW-1	Use in electroplating - Professional <u>Further description of the use:</u> Contributing activity/technique for the environment : - Use in electroplating - Professional (ERC8c) Contributing activity/technique for the workers : - Closed continuous process with occasional controlled exposure (PROC 2) (PROC 2) - Open or semi-closed reaction process (PROC 4) (PROC 4) - Small scale handling/transfer of solutions/suspensions (PROC 9) (PROC 9) - Treatment of articles by dipping and pouring (PROC 13) (PROC 13) - Hand mixing (PROC 19) (PROC 19) Product Category used: PC 14: Metal surface treatment products Technical function of the substance: plating agents and metal surface treating agents use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: tonnes/year Subsequent service life relevant for that use: yes Link to the subsequent service life: Service life of treated articles Related assessment: use assessed in an own CSR



3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Substance: [Ruthenium trichloride \(hydrate\)](#)

Implementation: EU

Related composition: [Boundary Composition](#)

The substance is classified as follows:

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

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



Corrosive to metals:	Met. Corr. 1	H290: May be corrosive to metals.	
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Table 3.2. Classification and labelling according to CLP / GHS for health hazards

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

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

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

Labelling



Signal word: Danger

Hazard pictogram:

GHS05: corrosion



GHS07: exclamation mark



GHS09: environment



Hazard statements:

- H290: May be corrosive to metals.
- H302: Harmful if swallowed.
- H314: Causes severe skin burns and eye damage.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.

Precautionary statements:

- P101: If medical advice is needed, have product container or label at hand.
- P102: Keep out of reach of children.
- P103: Read carefully and follow all instructions.
- P234: Keep only in original packaging.
- P260: Do not breathe dust/fume/gas/mist/vapours/spray.
- P264: Wash ... thoroughly after handling.
- P270: Do not eat, drink or smoke when using this product.
- P273: Avoid release to the environment.
- P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
- P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.
- P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
- P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310: Immediately call a POISON CENTER/doctor/...
- P321: Specific treatment (see ... on this label).
- P330: Rinse mouth.



P363: Wash contaminated clothing before reuse.

P390: Absorb spillage to prevent material damage.

P391: Collect spillage.

P405: Store locked up.

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

P501: Dispose of contents/container to ...

Additional labelling requirements (CLP supplemental hazard statement):

EUH071: Corrosive to the respiratory tract.



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

No relevant information available.

4.1.2.2. Biodegradation in soil

No relevant information available.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

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

Table 4.1. Studies on adsorption/desorption

Method	Results	Remarks
adsorption / desorption: 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) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	2 (reliable with restrictions) key study 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, (full information in Annex II). 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)	2 (reliable with restrictions) key study read-across from



	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) Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	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 Test material Ruthenium, (full information in Annex II). 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: Ruthenium trichloride (hydrate) 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:

Koc at 20°C:

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

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:

Ruthenium trichloride hydrate (RuCl_3) is likely to be poorly absorbed after administration by the oral route, 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.

Absorption via the inhalation route 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 and the high water solubility. Noting the potential for disruption of the skin barrier caused by corrosion, a value of 20% 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 (%): 20

Absorption rate - inhalation (%): 100

Additional information:

Absorption

The dataset for toxicokinetics of ruthenium and its salts is very limited. However, most available studies have investigated the simple salt ruthenium (III) chloride (RuCl_3) hydrate.

In a series of studies, covering oral, intraperitoneal and intravenous administration to rodents, dogs and primates, the toxicokinetic profile of RuCl_3 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 $^{103}\text{RuCl}_3$ 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 56.7% of the RuCl_3 sample had a particle size $<100\text{ }\mu\text{m}$ (Walker and White, 2011). An MMAD value $<100\text{ }\mu\text{m}$ indicates that a significant proportion of the substance is likely to be inhalable. As a highly water soluble substance (1140 g/L; Gregory, 2014), any RuCl_3 reaching the lungs is likely to be absorbed through aqueous pores or be retained in the mucus and transported out of the respiratory tract.

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 RuCl_3 were identified. The high water solubility ($>1000\text{ g/L}$) 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 might be appropriate in this case; 10% is the lower of the two values provided by the guidance (ECHA, 2014).

However, RuCl_3 is classified as corrosive to the skin based on the results of two in vitro studies (on the solid and solution forms of the test substance). Thus, there is the potential for disruption to the skin barrier and, consequently, increased percutaneous absorption. On this basis, it could be argued that the higher ECHA default, 100%, is applicable.

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).

Overall, the various default values are somewhat conflicting. Absorption in the range of that indicated by ICMM (2007) seems to be too low when considering the likely skin barrier disruption. However, assuming 100% absorption could be considered as overestimating the dermal absorption potential, particularly considering the high water solubility. In the absence of experimental data, it is considered suitably health precautionary to take forward a value of 20% dermal absorption for use in CSA and DNEL derivation.

Distribution/Metabolism

Once absorbed, distribution of RuCl_3 throughout the body is expected based on a relatively low molecular weight ($\approx 200\text{--}250\text{ g/mol}$, depending on degree of hydration).

As no adverse toxicological effects were reported in repeated-dose and reproductive/developmental toxicity dietary studies in rats on RuCl_3 (Hargitai, 2017; Zelenak, 2017), no insights can be gained regarding potential tissue distribution.

Elimination (and Bioaccumulation)

Following oral administration of radiolabelled soluble ^{106}Ru (as $^{106}\text{RuCl}_3$) 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 $^{106}\text{RuCl}_3$, 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, administered $^{103}\text{RuCl}_3$ 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). RuCl_3 is considered to have only a low potential for bioaccumulation based on its predicted physico-chemical properties (especially a high water solubility of 1140 g/L).

Conclusion

Based on limited experimental data, physico-chemical properties, chemical structure and molecular weight, ruthenium chloride hydrate is likely to be poorly absorbed after administration by the oral route. Bioaccumulation is unlikely, and any absorbed RuCl_3 is expected to be rapidly excreted. Absorption via the inhalation route could be extensive. A high dermal bioavailability is unlikely, but the potential for increased percutaneous absorption of RuCl_3 – a known skin corrosive – as a result of skin barrier disruption is noted.

Absorption values of 1%, 20% 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.

References (for which an ESR has not been created in IUCLID):

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

Furchner JE, Richmond CR and Drake GA (1971). Comparative metabolism of radionuclides in mammals – VII. Retention of ^{106}Ru in the mouse, rat, monkey and dog. *Health Physics* 21, 355-365.

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

Yamagata N, Iwashima K, Iinuma TA, Watari K and Nagai T (1969). Uptake and retention experiments of rutherenium in man – I. *Health Physics* 16, 159-166.

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

The results of studies on acute toxicity after oral administration are summarised in the following table:

Table 5.1. Studies on acute toxicity after oral administration

Method	Results	Remarks
rat [common species] (Bor: WISW (SPFCpb)) male/female oral: gavage according to OECD Guideline 401 (Acute Oral Toxicity) [before 2002] ; according to EU Method B.1 (Acute Toxicity (Oral))	LD50: 723 mg/kg bw (male) LD50: 525 mg/kg bw (female) LD50: 595 mg/kg bw (male/female)	1 (reliable without restriction) key study experimental study Test material 14898-67-0 / 14898-67-0 / 604-667-4;



		Rutheniumchloride hydrate, (full information in Annex II). Reference Berthold K 1993
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5.2.1.2. Acute toxicity: inhalation

No relevant information available.

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is classified as corrosive to the skin [study scientifically not necessary / other information available] - In accordance with Column 2 of REACH Annex VIII, acute toxicity by a second route does not need to be conducted if the substance is classified as corrosive to the skin.

5.2.1.3. Acute toxicity: dermal

No relevant information available.

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is classified as corrosive to the skin [study scientifically not necessary / other information available] - In accordance with Column 2 of REACH Annex VIII, acute toxicity by a second route does not need to be conducted if the substance is classified as corrosive to the skin.

5.2.1.4. Acute toxicity: other routes

No relevant information available.

5.2.2. Human information

No relevant information available.

5.2.3. Summary and discussion of acute toxicity

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

In an OECD guideline study, the acute oral LD50 value for ruthenium trichloride hydrate was determined to be 595 mg/kg bw in rats (Berthold, 1993).

No relevant acute dermal or inhalation toxicity data were identified.



Value used for CSA:

Acute oral toxicity:
adverse effect observed
(LD50) 595mg/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 toxicity of ruthenium (III) chloride hydrate was investigated in rats, in an OECD Test Guideline 401 study, conducted according to GLP. Animals (5/sex/group) were administered the test substance (in water) by oral gavage at doses of 215, 464 or 1000 mg/kg bw, and observed for up to 14 days. There were no deaths in the low dose group, while two females died in the mid-dose group and all animals died at the highest tested dose. Clinical signs of toxicity were seen in all treated animals. Gross pathology indicated effects in the stomach mucosa at the higher two doses. The acute oral LD50 was determined (using probit analysis) to be 723 mg/kg bw in male rats (95% CI 379-1131 mg/kg bw), 525 mg/kg bw in females (95% CI 272-1095 mg/kg bw) and 595 mg/kg bw for both sexes combined (95% CI 444-808 mg/kg bw) (Berthold, 1993).

No relevant acute dermal or inhalation toxicity data were identified. However, acute toxicity testing by a second route is not considered appropriate as ruthenium trichloride hydrate is considered corrosive.

Justification for classification or non classification:

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

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

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

No relevant information available.



5.3.1.2. Human information

No relevant information available.

5.3.2. Eye

5.3.2.1. Non-human information

No relevant information available.

Data waiving

Information requirement: Eye Irritation

Reason: study scientifically not necessary / other information available

Justification: the study need not be conducted because the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes [study scientifically not necessary / other information available] ; In accordance with Column 2 of REACH Annex VIII, the study does not need to be conducted as the substance is a strong acid ($\text{pH} < 2.0$) and is classified as corrosive to the skin.

5.3.2.2. Human information

No relevant information available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No relevant information available

5.3.3.2. Human information

No relevant information available.

5.3.4. Summary and discussion of irritation

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

In two in vitro membrane barrier tests (CORROSITEX™ Assays), conducted according to OECD Test Guideline 435 and to GLP, ruthenium trichloride hydrate displayed mean breakthrough times of 24.3 and 12.6 minutes when tested as a solid (Lehmeier, 2013a) and in aqueous solution (Lehmeier, 2013b), respectively, and was considered corrosive to the skin.

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

Value used for CSA:

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

Additional information:



No relevant human irritation/corrosion data were identified.

In two good quality GLP studies, conducted according to OECD Test Guideline 435, the potential of ruthenium trichloride hydrate, as a solid or in solution, to induce skin corrosion was assessed in the “in vitro membrane barrier test (CORROSITEX™ Assay)”. The test items were placed on top of a BIOBARRIER membrane which was sat on a chemical detection system (CDS) in a vial. Corrosivity is determined on the ability (measured by the time taken) of a chemical to break through the barrier and subsequently activate the underlying CDS (as seen by a colour or consistency change).

The mean time required for ruthenium trichloride hydrate (solid) to activate the CDS was 24.31 minutes (mean of 4 replicates). The test substance is therefore classified as “corrosive” sub category 1B, according to EU CLP criteria (EC 1272/2008), as the mean time to activate the CDS was between 3-60 minutes (category 1) (Lehmeier, 2013a).

For ruthenium trichloride hydrate solution, the mean time required to activate the CDS was 12.61 minutes (mean of 4 replicates). The test substance is therefore classified as “corrosive” sub category 1B, according to EU CLP criteria (EC 1272/2008), as the mean time to activate the CDS was between 3-60 minutes (category 1) (Lehmeier, 2013b).

No eye or respiratory tract data were identified. However, eye irritation testing is not considered appropriate as ruthenium trichloride hydrate is classified as corrosive to the skin.

Justification for classification or non classification:

Based on the results of the available reliable in vitro skin corrosion studies, ruthenium trichloride hydrate should be classified as corrosive to the skin (category 1B) according to EU CLP criteria (EC 1272/2008). Substances that are corrosive to the skin are considered as leading to serious damage to the eyes. Consequently, ruthenium trichloride hydrate should be classified for eye effects in Category 1 according to EU CLP criteria (EC 1272/2008).

5.4. Corrosivity

5.4.1. Non-human information

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

Table 5.2. Studies on skin irritation related to corrosivity

Method	Results	Remarks
Tissue studied: skin corrosion: in vitro / ex vivo Not applicable. (Not applicable.) Coverage: Not applicable. (Not	Category 1B (corrosive) based on GHS criteria CORROSITEX time (minutes) mean of 4 replicates. Value: 24.31	1 (reliable without restriction) key study experimental study



applicable.) Vehicle: unchanged (no vehicle) according to OECD Guideline 435 (In Vitro Membrane Barrier Test Method for Skin Corrosion)	(positive indication of irritation)	Test material 10049-08-8 / 233-167-5; 14898-67-0 / 14898-67-0 / 604-667-4, Form: solid: particulate/powder - migrated information: powder (full information in Annex II). Reference Lehmeier D 2013
Tissue studied: skin corrosion: in vitro / ex vivo Not applicable. (Not applicable.) Coverage: Not applicable. (Not applicable.) Vehicle: unchanged (no vehicle) according to OECD Guideline 435 (In Vitro Membrane Barrier Test Method for Skin Corrosion)	Category 1B (corrosive) based on GHS criteria CORROSITEX time (minutes) mean of 4 replicates. Value: 12.61 (positive indication of irritation)	1 (reliable without restriction) key study experimental study Test material 10049-08-8 / 233-167-5; 14898-67-0 / 14898-67-0 / 604-667-4, Form: solution (full information in Annex II). Reference Lehmeier D 2013

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

No relevant information available.

Data waiving

Information requirement: Skin Sensitisation



Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is a strong acid ($\text{pH} \leq 2.0$) or base ($\text{pH} \geq 11.5$) [study scientifically not necessary / other information available] ; In accordance with Column 2 of REACH Annex VIII, the study does not need to be conducted as the substance is a strong acid ($\text{pH} < 2.0$) and is classified as corrosive to the skin.

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

No relevant skin or respiratory tract sensitisation data were identified. However, skin sensitisation testing is not considered appropriate as ruthenium trichloride hydrate is classified as corrosive to the skin.

Value used for CSA: no study available
Additional information:

No relevant skin sensitisation data were identified. However, such testing is not considered appropriate as ruthenium trichloride hydrate is classified as corrosive to the skin.

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:**

No skin or respiratory tract sensitisation data are available. As such, there is no evidence to classify it as a skin or respiratory sensitiser 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 5.3. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks
rat [common rodent species] (Wistar [rat]) male/female short-term repeated dose toxicity: oral (oral: feed) 0ppm 500ppm 1500ppm 5000ppm 15000ppm Vehicle: Exposure: 28 days. (Constant (dietary).) according to OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents)	NOAEL: 5000 ppm (male/female) based on: (test mat.) body weight and weight gain - Reduced body weight gain seen in high dose (15,000 ppm) treated males.	1 (reliable without restriction) key study experimental study Test material Ruthenium (III) chloride hydrate, Form: solid: particulate/powder (full information in Annex II). Reference Zelenák V 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 407 repeated dose oral toxicity study, rats were fed diets containing 0, 500, 1500, 5000 or 15,000 ppm ruthenium trichloride hydrate for 28 days. Males in the highest dose group had reduced body weight gain and reduced food conversion efficiency compared to controls. There were no other adverse effects in these animals, and no effects on clinical signs, pathology, organ weights or histopathology in any treated animals. The study NOAEL was 5000 ppm (equivalent to about 407 mg/kg bw/day) (Zelenák, 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: 407mg/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 an OECD Test Guideline 407 repeated dose oral toxicity study, conducted according to GLP, Wistar rats (5/sex/group) were fed ruthenium trichloride hydrate at concentrations of 0, 500, 1500, 5000 or 15,000 ppm (equivalent to approximately 0, 40.6, 124, 407 or 1238 mg/kg bw/day) for 28 days. Male rats fed the highest dietary concentration showed reduced body weight gain compared to controls. These animals also demonstrated a statistically significant reduction in food conversion efficiency. No other significant differences in body weight or body weight gain were reported, although high dose females showed reduced growth for the first week only. There were no adverse effects on food consumption, clinical signs of toxicity, behaviour (functional neurological assessment), haematology, clinical biochemistry, gross pathology, organ weights or histopathology. The no-observed-adverse-effect level (NOAEL) of ruthenium trichloride in rats after 28 days' administration in the diet was 5000 ppm (approximately 407 mg/kg bw/day), on the basis of reduced body weight gain in treated males. On this basis, a study NOAEL of 5000 ppm (about 407 mg/kg bw/day) was established (Zelenák, 2017).

In an OECD Test Guideline 421 reproductive and developmental toxicity screening study involving dietary exposure to ruthenium trichloride hydrate at up to 15,000 ppm for at least 29 days, the systemic NOAEL was 5000 ppm (419 mg/kg bw/day), based on reduced growth in males at the highest tested dose (Hargitai, 2017).



According to REACH Annex VIII (EC 1907/2006), repeated dose toxicity studies only need to be conducted on one species taking into consideration the most appropriate route of administration regarding human exposure.

Justification for classification or non classification:

No adverse systemic effects were seen in reliable guideline studies (28-day oral repeated dose and a reproductive/developmental screening assay) with ruthenium trichloride hydrate at more than 400 mg/kg bw/day. As such, the results of these studies indicate that classification of this substance as STOT-RE is not required, according to EU CLP criteria (EC 1272/2008).

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

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

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

Table 5.4. In vitro genotoxicity studies:

Method	Results	Remarks
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria] (with and without met. act.) Test concentrations: Range-finder experiment and mutation experiment 1: 5, 16, 50, 160, 500, 1600 and 5000 µg/plate. Mutation experiment 2: 160, 300, 625, 1250, 2500 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 according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity - In Mutation Experiment 1: from 500 to 5000 µg/plate -S9 and from 1600-5000 µg/plate +S9; Mutation Experiment 2: 2000 and/or 5000 µg/plate -S9 and +S9 vehicle controls valid: valid negative controls valid: not applicable positive controls valid: valid Test results: negative for S. typhimurium TA 102 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: cytotoxicity - In Mutation Experiment 1: from 500 to 5000 µg/plate -S9 and from 1600-5000 µg/plate +S9; Mutation Experiment 2: 2000 µg/plate -S9 and +S9 vehicle controls valid: valid negative controls valid: not applicable positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	1 (reliable without restriction) key study experimental study Test material Ruthenium (III) chloride hydrate / 14898-67-0, Form: solid: particulate/powder - migrated information: powder (full information in Annex II). 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] (with and without met. act.) Test concentrations: Cytotoxicity range-finder experiment: 62.5, 125, 250, 500, 1000 and 2000 µg/mL (both with and without S9) Experiment 1: 12.5, 25, 50, 100, 200 and 300 µg/mL (without S9) and 12.5, 25, 50, 100, 200, 300, 400 and 500 µg/mL (with S9) Experiment 2: 25, 50, 100, 150, 200, 250, 300 and 400 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]	Test results: negative for mouse lymphoma L5178Y cells [mammalian cell line]; met. act.: with and without genotoxicity: negative cytotoxicity: no cytotoxicity, but tested up to precipitating concentrations - No precipitate was observed at the time of treatment but following the 3 hour incubation period, precipitate was observed at the highest three concentrations in the absence and presence of S9 (500 to 2000 µg/mL in the cytotoxicity range finder experiment) vehicle controls valid: valid negative controls valid: not applicable positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	1 (reliable without restriction) key study experimental study Test material 14898-67-0 / 14898-67-0 / 604-667-4; Ruthenium (III) chloride hydrate, Form: solid: particulate/powder - migrated information: powder (full information in Annex II). 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 peripheral blood lymphocytes [primary culture] (with and without met. act.) Test concentrations: Cytotoxicity Range-Finder Experiment, 3+21 -S9, 3+21 +S9, 24+0 -S9: 7.256 to 2000 µg/mL Micronucleus Experiment, 3+21 -S9, 3+21 +S9: 10 to 1000 µg/mL Micronucleus Experiment, 24+0 -S9: 30 to 1000 µg/mL Positive control substance(s): mitomycin C Positive control substance(s): cyclophosphamide Positive control substance(s): noscapine according to OECD guideline 487 (In Vitro Mammalian Cell Micronucleus Test)	Test results: negative - 3+21 hours -/+S9; 24+0 hours -S9 for lymphocytes: human peripheral blood lymphocytes [primary culture]; met. act.: with and without genotoxicity: negative - 3+21 hours -/+S9; 24+0 hours -S9 cytotoxicity: no cytotoxicity, but tested up to precipitating concentrations vehicle controls valid: valid negative controls valid: not applicable positive controls valid: valid Remarks: all strains/cell types tested - Migrated from field 'Test system'.	1 (reliable without restriction) key study experimental study Test material 14898-67-0 / 14898-67-0 / 604-667-4; Ruthenium (III) chloride hydrate, Form: solid: particulate/powder - migrated information: powder (full information in Annex II). Reference Lloyd M 2016

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, ruthenium trichloride hydrate failed to induce an increase in mutation frequency in five histidine-requiring *Salmonella typhimurium* strains (TA98, TA100, TA1535, TA1537 and TA102) when tested at concentrations of up to 5000 µg/plate or up to the limit of cytotoxicity, in the absence and presence of S9 (McGarry, 2016).

In an in vitro mammalian cell gene mutation assay, conducted in accordance with OECD Test Guideline 476 and to GLP, ruthenium trichloride hydrate failed to induce biologically relevant increases in mutations at the *hprt* locus of L5178Y mouse lymphoma cells when tested up to precipitating concentrations in two independent experiments, each 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, ruthenium trichloride hydrate 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, ruthenium trichloride hydrate 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:

Ruthenium trichloride hydrate 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). The highest concentrations of test article analysed were up to 5000 µg/plate or up to the limit of cytotoxicity and were determined following a preliminary toxicity range-finder experiment. In experiment 1 a plate incorporation protocol was used; the experiment was repeated using a pre-incubation step. Appropriate vehicle and positive control cultures were included in the test system under each treatment condition. There was no evidence of mutagenicity in any strain with or without S9 in either experiment. Some evidence of toxicity was observed at 1600 and/or 5000 µg/plate with the plate incorporation protocol and at 1250 and/or 2500 µg/plate with the pre-incubation protocol. Vehicle and positive controls performed as expected. It is concluded that ruthenium trichloride hydrate 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), ruthenium trichloride hydrate 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 500 µg/mL and above. In the main test, cells were exposed to test material for 3 hours in two independent experiments, each in the absence and presence of S9. Concentrations of 12.5-300 µg/mL and 25-500 µg/mL (Experiments 1 and 2, respectively) were used. The highest concentrations analysed, limited by precipitation, were 300 and 500 µg/mL (Experiment 1, without and with S9, respectively) exhibiting 107% and 72% relative survival (RS), respectively. In Experiment 2, the highest concentrations analysed was 400 µg/mL, both without and with S9, which gave RS values of 103% and 86%, respectively. No significant increases in mutant frequency (MF) over the concurrent controls were observed following treatment with ruthenium (III) chloride hydrate 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 weakly statistically significant linear trend ($p < 0.05$) in MF was observed in the absence of S9 in Experiment 2, this was considered not biologically relevant since there were no statistically significant increases in MF at any concentration analysed and the effect was not reproduced between experiments. Overall, ruthenium trichloride hydrate 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).

Ruthenium trichloride hydrate 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 1000 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. The concentrations selected for analysis were 125, 150 and 200 µg/mL (3-hour treatment) and 30, 60 and 90 µg/mL (24-hour treatment). There was no evidence of an increase in micronucleus frequency with or without S9 following treatment of cells with ruthenium trichloride hydrate for 3 hours and/or 24 hours. Some evidence of cytotoxicity was observed at 200 µg/mL though this was not statistically significant. Vehicle and positive controls performed as expected. Overall, ruthenium trichloride hydrate 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).

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

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

No relevant information available.

5.8.1.2. Carcinogenicity: inhalation

No relevant information available.

5.8.1.3. Carcinogenicity: dermal



No relevant information available.

5.8.1.4. Carcinogenicity: other routes

No relevant information available.

5.8.2. Human information

No relevant information available.

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

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

Table 5.5. Studies on fertility

Method	Results	Remarks
rat (Wistar [rat]) male/female screening for reproductive / developmental toxicity oral: feed 0ppm (nominal) Control group receiving the basal (control) diet. 100ppm (nominal) “Low dose” 300ppm (nominal) “Mid dose” 1000ppm (nominal) “High dose” Vehicle: Exposure: Males were treated for 29 days (14 days pre-mating and 15 days mating/post-mating period). Females were treated for 14 days pre-mating, for up to 14 days in the mating period, through gestation (22-24 days) and up to and including the day of necropsy (13 days post-partum dosing); non-pregnant females were sacrificed on day 49. (Constant (dietary)) according to OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	First parental generation (P0) NOAEL - Fertility and reproductive parameters (PO) 1276 mg/kg bw/day (actual dose received) (male/female) based on: no effects at high dose NOAEL - Systemic toxicity (PO) 419 mg/kg bw/day (actual dose received)) (male) based on: body weight and weight gain [general toxicity] NOAEL - Systemic toxicity (PO) 1276 mg/kg bw/day (actual dose received)) (female) based on: no effects at high dose F1 generation NOAEL - Pre- and post-natal development of pups : 1276 mg/kg bw/day (actual dose received) (male/female) based on: no effects at high dose Overall reproductive toxicity no Lowest effective dose / concentration Relation to other toxic effects:	1 (reliable without restriction) key study experimental study Test material Ruthenium chloride / Ruthenium (III) chloride hydrate / 14898-67-0, Form: solid (full information in Annex II). Reference Hargitai J 2017

Toxicity to reproduction: other studies

No relevant information available.

5.9.1.2. Human information



No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

No relevant information available.

5.9.2.2. Human information

No relevant information available.

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

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

In an OECD Test Guideline 421 reproduction and developmental toxicity screening study, to GLP, parental (F0) rats (12/sex/group) were fed diets containing ruthenium trichloride hydrate at concentrations of 0, 1500, 5000 or 15,000 ppm for at least 29 days. No adverse effects on any measured reproductive or fertility parameters of parent males and females (F0 animals) were observed at any dose. The reproductive NOAEL was the highest tested dose of 15,000 ppm (about 1276 mg/kg bw/day) (Hargitai, 2017).

Value used for CSA (route: oral):

no adverse effect observed (NOAEL): 1276mg/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 reproductive and developmental toxicity screening study, conducted according to OECD Test Guideline 421 and to GLP, Wistar rats (12/sex/group) were fed ruthenium trichloride hydrate at concentrations of 0, 1500, 5000 or 15,000 ppm. Males were dosed for 29 days (14 days pre-mating and 15 days through the mating and post-mating periods). Females were dosed for 14 days pre-mating, through mating (up to 14 days), gestation (22-24 days) and up to post-partum day 13 (around 8 weeks in total). There were no reported changes to reproductive parameters (including number of implantations, number of pups, fertility and gestation indices, reproductive performance as well as intrauterine and total mortality). Test item administration was not associated with any gross changes, or microscopic findings in the reproductive organs, at up to the highest tested dose. Thyroid hormone analysis was also unaffected by treatment. The reproductive NOAEL was the highest tested dose of 15,000 ppm (about 1276 mg/kg bw/day) (Hargitai, 2017).

Developmental toxicity



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

In an OECD Test Guideline 421 reproduction and developmental toxicity screening study, to GLP, parental (F0) rats (12/sex/group) were fed diets containing ruthenium trichloride hydrate at concentrations of 0, 1500, 5000 or 15,000 ppm for at least 29 days. No adverse effects on development of offspring (F1 generation) were observed at any dose. The developmental NOAEL was the highest tested dose of 15,000 ppm (about 1276 mg/kg bw/day) (Hargitai, 2017).

Value used for CSA (route: oral):

no adverse effect observed (NOAEL): 1276mg/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 reproductive and developmental toxicity screening study, conducted according to OECD Test Guideline 421 and to GLP, Wistar rats (12/sex/group) were fed ruthenium trichloride hydrate at concentrations of 0, 1500, 5000 or 15,000 ppm. Males were dosed for 29 days (14 days pre-mating and 15 days through the mating and post-mating periods). Females were dosed for 14 days pre-mating, through mating (up to 14 days), gestation (22-24 days) and up to post-partum day 13 (around 8 weeks in total). There were no adverse effects on the F1 offspring viability, clinical signs or developmental effects. Body and organ weights were also unaffected, while histopathological and hormone evaluation of the thyroid did not reveal any adverse findings. The developmental NOAEL was the highest tested dose of 15,000 ppm (1276 mg/kg bw/day) (Hargitai, 2017).

Justification for classification or non classification:

No adverse effects on reproductive parameters (sexual function or fertility) or development of offspring were seen in a reliable guideline reproductive/developmental toxicity screening assay with ruthenium trichloride hydrate. As such, classification of this substance for reproductive toxicity is not required, according to EU CLP criteria (EC 1272/2008).

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

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No relevant information available.



5.10.1.2. Immunotoxicity

No relevant information available.

5.10.1.3. Specific investigations: other studies

No relevant information available.

5.10.1.4. Additional toxicological effects

No relevant information available.

5.10.2. Human information

No relevant information available.

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

5.11.1. Overview of typical dose descriptors for all endpoints

Table 5.6. Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type
Acute toxicity	oral	adverse effect observed (LD50): 595mg/kg bw
Acute toxicity	dermal	no study available
Acute toxicity	inhalation	no study available
Irritation / Corrosivity	skin	adverse effect observed (corrosive)
Irritation / Corrosivity	eye	no study available
Irritation / Corrosivity	resp. tract	no study available
Sensitisation	skin	no study available
Sensitisation	resp. tract	no study available
Repeated dose toxicity	oral	no adverse effect observed (NOAEL): 407mg/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): 1276mg/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): 1276mg/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 5.7. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.38mg/m ³	repeated dose toxicity (Oral)
Inhalation	Systemic effects - Acute	no hazard identified	
Inhalation	Local effects - Long-term	medium hazard (no threshold derived)	skin irritation/corrosion
Inhalation	Local effects - Acute	medium hazard (no threshold derived)	skin irritation/corrosion
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.27mg/kg bw/day	repeated dose toxicity (Oral)
Dermal	Systemic effects - Acute	no hazard identified	
Dermal	Local effects - Long-term	medium hazard (no threshold derived)	skin irritation/corrosion
Dermal	Local effects - Acute	medium hazard (no threshold derived)	skin irritation/corrosion
Eyes	Local effects	medium hazard (no threshold derived)	



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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 28-day repeated-dose dietary study (with support from a 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

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 28-day repeated-dose dietary study (with support from a 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 ruthenium trichloride hydrate in laboratory animals are available, route-to-route extrapolation to calculate an inhalation DNEL from a reliable repeated-dose oral toxicity study 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 407) 28-day dietary toxicity study, rats received ruthenium trichloride hydrate at concentrations of 0, 500, 1500, 5000 or 15,000 ppm. Males in the highest dose group showed reductions in growth and food conversion efficiency compared to controls. There were no other adverse effects in these animals, and no effects on clinical signs, pathology, organ weights or histopathology in any other treated animals. The study NOAEL was the dietary concentration of 5000 ppm (about 407 mg/kg bw/day) (Zelenák, 2017).

In another guideline study (OECD TG 421; reproductive/developmental toxicity screening assay), parental males also displayed reduced growth at the highest tested dose (15,000 ppm), resulting in a systemic NOAEL of 5000 ppm (419 mg/kg bw/day). No effects on reproductive parameters, gross/microscopic changes in the reproductive organs or indications of foetal toxicity were observed at any dose level. Thus, the NOAEL for reproductive and developmental toxicity was 15,000 ppm (1276 mg/kg bw/day) (Hargitai, 2017). The possible limitations of this study, as reassurance of an absence of reproductive effects, are acknowledged. ECHA (2012) guidance recommends “application of an additional assessment factor of 2 to 5, decided on a case-by-case basis that should account for the limitations of this study”. Even applying the most conservative of these (i.e. an additional AF of 5) results in a DNEL higher than that derived for repeated dose effects (as the AF of 6 for differences in duration of exposure would not also be required).

The systemic NOAEL of 407 mg/kg bw/day, considered protective of fertility and developmental effects, is most critical and equates to a NOAEL of 162.8 mg/kg bw/day when expressed as elemental ruthenium (assuming a metal concentration of around 40%).

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 56.7% of the RuCl₃ sample had a particle size <100 µm (Walker and White, 2011). An MMAD value <100 µm indicates that a significant proportion of the substance is likely to be inhalable. As a highly water soluble substance (1140 g/L; Gregory, 2014), any RuCl₃ reaching the lungs is likely to be absorbed through aqueous pores or be retained in the mucus and transported out of the respiratory tract.

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) = 407 mg/kg bw/day * (1/0.38 m³/kg bw/day) * (1/100) * (6.7 m³ [8h]/10 m³ [8h]) = 7.18 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 = 7.18*4 = 28.7 mg/m³

Application of the appropriate assessment factors (overall AF 75) to this corrected inhaled NOAEC gives a systemic long-term inhalation DNEL for ruthenium trichloride hydrate of 0.38 mg/m³. This equates to an elemental ruthenium exposure of 0.15 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 ruthenium trichloride hydrate. In a guideline (OECD TG 401) acute oral toxicity study in rats, the LD₅₀ value was determined to be 595 mg/kg bw (Berthold, 1993). The compound is classified in for acute oral toxicity in Category 4 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, ruthenium trichloride hydrate is classified in Category 4, 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 ruthenium trichloride hydrate in humans or laboratory animals. Consequently, no worker-DNELs for long-term or acute local effects in the respiratory tract have been calculated.

Ruthenium trichloride hydrate is classified as corrosive to the skin (Category 1B). Despite the lack of respiratory tract irritation data, it would appear prudent to assume that this substance would also irritate the respiratory tract if inhaled at sufficient levels/durations. According to ECHA (2016a) guidance “substances classified for skin corrosion Category 1B/1C in CLP” or “Serious eye damage Category 1 in CLP “... “which relate to corrosive or severe irritant effects to the eye or irritant effects to the eyes, respiratory tract and skin simultaneously, are allocated to the moderate hazard band on the basis that exposure to such corrosives, eye



damaging or irritant substances should be well-controlled". Therefore, consider recommended Risk Management Measures/Operational Conditions (RMMs/OCs) in Table E.3-1 of ECHA (2016a).

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

As no relevant data on effects of repeated dermal exposure to ruthenium trichloride hydrate in humans or laboratory animals are available, route-to-route extrapolation to calculate a dermal DNEL from a reliable repeated-dose oral toxicity study 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"] (Zelenák, 2017).

The oral NOAEL of 407 mg/kg bw/day equates to a NOAEL of 162.8 mg/kg bw/day for elemental ruthenium (assuming a metal concentration of around 40%), 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 RuCl₃ were identified. The high water solubility (>1000 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 might be appropriate in this case; 10% is the lower of the two values provided by the guidance (ECHA, 2014).

However, RuCl₃ is classified as corrosive to the skin based on the results of two in vitro studies (on the solid and solution forms of the test substance) (Lehmeier, 2013a,b). Thus, there is the potential for disruption to the skin barrier and, consequently, increased percutaneous absorption. On this basis, it could be argued that the higher ECHA default, 100%, is applicable.

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).

Overall, the various default values are somewhat conflicting. Absorption in the range of that indicated by ICMM (2007) seems to be too low when considering the likely skin barrier disruption. However, assuming 100% absorption could be considered as overestimating the dermal absorption potential, particularly considering the high water solubility. In the absence of experimental data, it is considered suitably health precautionary to take forward a value of 20% dermal absorption for the current safety assessment.

Dose descriptor starting point (after route to route extrapolation) = $\text{NOAEL} \times (\text{ABS}[\text{oral-rat}] / \text{ABS}[\text{der-human}])$



= 407 mg/kg bw/day*(1%/20%) = 20.4 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 ruthenium trichloride hydrate of 0.27 mg/kg bw/day, which equates to an elemental ruthenium exposure of 0.11 mg/kg bw/day.

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

In guideline (OECD TG 435) in vitro membrane barrier tests, ruthenium trichloride hydrate (when tested as a solid and in aqueous solution) was classified as corrosive sub-category 1B under GHS, on the basis of mean breakthrough times of about 24 and 13 minutes, respectively (Lehmeier, 2013a,b). No dose-response data was available from which to derive a DNEL, therefore a qualitative assessment was considered appropriate. At worst this would be considered in the moderate hazard band according to ECHA (2016a) guidance. Therefore, consider recommended RMMs/OCs in Table E.3-1 of ECHA (2016a).

No information regarding the skin sensitisation hazard of ruthenium trichloride hydrate was available; such testing is not considered appropriate as the substance is classified as corrosive to the skin.

Hazard for the eyes

According to ECHA guidance on the application of CLP criteria (ECHA, 2015), “if a substance or mixture is classified as Skin corrosive Category 1 then serious damage to eyes is implicit and there is no need to proceed with classification for eye effects”. Ruthenium trichloride hydrate is classified for skin effects as corrosive sub-category 1B. Consequently, the compound is classified for eye effects in Category 1 under EU CLP.

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

References (for which a ESR has not been created in IUCLID)

ECHA (2009). European Chemicals Agency. Guidance in a Nutshell: Chemical Safety Assessment. Reference: ECHA-09-B-15-EN. September 2009.
http://echa.europa.eu/documents/10162/13632/nutshell_guidance_csa_en.pdf

ECHA (2011). European Chemicals Agency. Guidance on information requirements and chemical safety assessment Part B: Hazard assessment. Reference: ECHA-11-G-16-EN. Version 2.1. December 2011.
https://echa.europa.eu/documents/10162/13643/information_requirements_part_b_en.pdf



ECHA (2012). European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health. Reference: ECHA-2010-G-19-EN. Version 2.1. November 2012.http://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf

ECHA (2014). European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Chapter R.7c: endpoint specific guidance. Version 2.0. November 2014.http://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf

ECHA (2016a). European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Part E: Risk Characterisation. ECHA-12-G-04-EN. Version 3.0. May 2016.http://echa.europa.eu/documents/10162/13632/information_requirements_part_e_en.pdf

ECHA (2016b). European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Chapter R.16: Environmental exposure assessment. Version 3.0. February 2016.http://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

Furchner JE, Richmond CR and Drake GA (1971). Comparative metabolism of radionuclides in mammals – VII. Retention of ¹⁰⁶Ru in the mouse, rat, monkey and dog. Health Physics 21, 355-365.

ICMM (2007). International Council on Mining & Metals. Health risk assessment guidance for metals. September 2007.<http://www.icmm.com/document/144>

Yamagata N, Iwashima K, Iinuma TA, Watari K and Nagai T (1969). Uptake and retention experiments of radioruthenium in man – I. Health Physics 16, 159-166.

Table 5.8. Hazard conclusions for the general population

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



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

Inhalation Systemic effects - Long-term**Inhalation Systemic effects - Acute****Inhalation Local effects - Long-term****Inhalation Local effects - Acute****Dermal Systemic effects - Long-term****Dermal Systemic effects - Acute****Dermal Local effects - Long-term****Dermal Local effects - Acute****Oral Systemic effects - Long-term**



Oral Systemic effects - Acute

Discussion:

DNELs have been derived only for workers, not for consumers/general population. During assessment of the identified uses for ruthenium trichloride hydrate, 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, ruthenium trichloride hydrate 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 ruthenium trichloride hydrate 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: Ruthenium trichloride (hydrate)

Related composition: Ruthenium trichloride (hydrate) (Boundary composition) (solid: particulate/powder)

Classification: data conclusive but not sufficient for classification

6.2. Flammability

Flammability

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

Table 6.1. Information on flammability

Method	Results	Remarks
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 gasses (lower and upper explosion limits): Aerosols: 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) Pyrophoric solids: Pyrophoric liquid: Self-heating substances/mixtures: Substances/ mixture which in contact with water emit flammable gases: Remarks: Pile failed to ignite during the two minutes that the Bunsen flame was applied.	1 (reliable without restriction) key study experimental study Test material Ruthenium trichloride (hydrated solid), Form: solid: particulate/powder - migrated information: powder (full information in Annex II). Reference Walker JA, White DF 2011

Discussion

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

Flammability.

Key value for chemical safety assessment: Flammability: not classified

Ruthenium trichloride (hydrate) is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.

**Additional information:**

Walker and White (2011) is a GLP compliant study following UN method N1 and is considered suitable for use as the key study for this endpoint. Ruthenium trichloride (hydrate) 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: Ruthenium trichloride (hydrate)

Related composition: Ruthenium trichloride (hydrate) (Boundary composition) (solid: particulate/powder)

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

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

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

Justification for classification or non-classification:

Ruthenium trichloride (hydrate) 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 min) according to UN Manual of Tests and Criteria: Test O.1 (Test for oxidizing solids)	Evaluation of results: GHS criteria not met Test results: Oxidising solids: 1:1 sample-to-cellulose ratio: mean burning time: (mixture does not ignite and burn) 4:1 sample-to-cellulose ratio: mean burning time: (mixture does not ignite and burn) Remarks: Results of 3:7 (by mass) reference mixture Potassium bromate and cellulose	1 (reliable without restriction) key study experimental study Test material Rhodium triiodide, (full information in Annex II). Reference Atwal SS, Tremain SP 2011



	Test Number	Burnin g time (s)	Observ ations		
	1	147	Orange and blue flame, spitting and splutter ing leaving a dark grey ash		
	2	139	Orange and blue flame, spitting and splutter ing leaving a dark grey ash		
	3	116	Orange and blue flame, spitting and splutter ing leaving a dark grey ash		
	4	133	Orange and blue flame, spitting and splutter ing leaving a dark grey ash		
	5	145	Orange and blue flame, spitting		



			and spluttering leaving a dark grey ash	
	Results of 4:1 (by mass) test item and cellulose mixture			
	1	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied	
	2	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied	
	3	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied	



	4	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied		
	5	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied		
	Results of 1:1 (by mass) test item and cellulose mixture				
	1	-	Grey smoke, no sign of ignition during the 3 minutes the power was applied		
	2	-	Grey smoke, no sign of ignition during the 3 minutes the		



			power was applied	
	3	-	Grey smoke, no sign of ignition during the 3 mintues the power was applied	
	4	-	Grey smoke, no sign of ignition during the 3 mintues the power was applied	
	5	-	Grey smoke, no sign of ignition during the 3 mintues the power was applied	
	The 4:1 and 1:1 test item:cellulose mixtures did not ignite and burn during the 3 minutes that the power was applied indicating test item is not an oxidising solid.			
oxidising solids	Evaluation of results: GHS criteria not met Test results: Oxidising solids: 1:1 sample-to-cellulose ratio: mean burning time: (mixture does not ignite and burn) 4:1 sample-to-cellulose ratio: mean burning time: (mixture does not ignite and burn) Remarks:			1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) Test material Rhodium triiodide, (full information in Annex II).



	Results of 3:7 (by mass) reference mixture Potassium bromate and cellulose			Reference Atwal SS, Tremain SP 2011
	Test Number	Burning time (s)	Observations	
	1	147	Orange and blue flame, spitting and spluttering leaving a dark grey ash	
	2	139	Orange and blue flame, spitting and spluttering leaving a dark grey ash	
	3	116	Orange and blue flame, spitting and spluttering leaving a dark grey ash	
	4	133	Orange and blue flame,	



			spitting and spluttering leaving a dark grey ash		
	5	145	Orange and blue flame, spitting and spluttering leaving a dark grey ash		
	Results of 4:1 (by mass) test item and cellulose mixture				
	1	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied		
	2	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied		



	3	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied		
	4	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied		
	5	-	Dark grey smoke, no sign of ignition during the 3 minutes the power was applied		
	Results of 1:1 (by mass) test item and cellulose mixture				
	1	-	Grey smoke, no sign of ignition during the 3 minutes		



			the power was applied		
	2	-	Grey smoke, no sign of ignition during the 3 mintues the power was applied		
	3	-	Grey smoke, no sign of ignition during the 3 mintues the power was applied		
	4	-	Grey smoke, no sign of ignition during the 3 mintues the power was applied		
	5	-	Grey smoke, no sign of ignition during the 3 mintues the power was applied		
The 4:1 and 1:1 test item:cellulose mixtures did not ignite and burn during the 3 minutes that the power was applied indicating test item is not an oxidising solid.					



Justification for type of information: REPORTING FORMAT FOR THE ANALOGUE APPROACH 1. HYPOTHESIS FOR THE ANALOGUE APPROACH For the assessment of oxidising properties substances have been split into groups of similar substances in the same oxidation state and with similar ligands. Oxidising properties of different substances within these groups are considered to be similar. Both the source and target substance are metals in the 3+ oxidation state with a halogen ligand and therefore read across is considered to be appropriate. 2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES) Source: Rhodium triiodide Target: Ruthenium trichloride (hydrate) 3. ANALOGUE APPROACH JUSTIFICATION For oxidising properties, the structural alerts indicating potential hazards are often associated with the ligands or counter-ions, and therefore the read across approach has taken into account the ligands associated with precious metal substances. Both rhodium triiodide and ruthenium trichloride have a metal in a 3+ oxidation state and a halogen ligand. Rhodium triiodide has been tested for oxidising properties and found to be non-oxidising. Based on the similarity of structure between this substance and ruthenium trichloride (hydrate), this result is read across to ruthenium trichloride (hydrate) and this substance is also considered to be non-oxidising.		

Discussion

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

Based on read across from rhodium triiodide, ruthenium trichloride is not considered to be oxidising.

Value used for CSA:

Oxidising properties: non oxidising

Additional information:

The oxidising properties of ruthenium trichloride are read across from another substance with a halogen ligand or counter ion in the 3+ oxidation state (rhodium triiodide). This substance is not oxidising based on GLP-compliant, guideline experimental study (Atwal and Tremain 2011). There is also supplementary evidence that other metal chlorides are also not oxidizing. For example, other Group VIII transition metals such as cobalt (II) chloride, iron (II), iron(III) and nickel(II) chloride. Copper(I) chloride from the adjacent Group IB is also not classified for oxidizing properties. There is therefore no evidence that any transition metal chloride is an oxidant. Supplementary evidence also comes from the non-transition metal chlorides and there is no evidence from two centuries of industrial and academic experience that these substances are oxidants.

On the basis of read-across ruthenium trichloride is not classified as an oxidising solid.

Classification according to GHS

Name: Ruthenium trichloride (hydrate)

Related composition: Ruthenium trichloride (hydrate) (Boundary composition) (solid: particulate/powder)

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

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

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

Justification for classification or non-classification:

Based on read across from a GLP-compliant, guideline study with rhodium triiodide, ruthenium trichloride is not classified for oxidising properties.



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 (*Raphidocelis subcapitata*) exposed to ruthenium trichloride (hydrate). 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): >0.38 mg/L element (meas. (geom. mean)) based on: mortality LC50 (96h): >0.94 mg/L test mat. (meas. (geom. mean)) based on: mortality	1 (reliable without restriction) key study experimental study Test material Ruthenium (III) Chloride hydrate, Form: solid (full information in Annex II). Reference Muth-Köhne E. 2016

Discussion

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

The 96-hour LC50 to zebrafish is > 0.94 mg test item L-1 (>0.38 mg Ru L-1), based on geometric mean measured concentrations.

Additional information:

A limit test to determine the acute toxicity of ruthenium (III) chloride hydrate to zebrafish (*Danio rerio*) was performed according to the OECD guideline 203 and the EEC method C.1 (Muth-Kohne 2016).

Based on the results from a rangefinder test, the fish were exposed to one nominal concentration of 10 mg test item L-1, corresponding to a nominal ruthenium concentration of 4.06 mg L-1 under semi-static conditions for 96 hours. Test media was renewed after 48 hours. Untreated dilution water was run in parallel as a control. Ten fish were placed in the treatment vessel and in the control. Effects on survival were determined after 24, 48, 72 and 96 hours. ICP-OES was used to analyse test solutions and as measured concentrations were not within 20% of nominal the effect assessment was based on geometric mean measured concentrations of aged and fresh test



solutions.

No mortality or any behavioural effects were observed at any observation time. Thus, the LC50 was determined to be > 0.94 mg test item L-1 (>0.38 mg Ru L-1), based on geometric mean measured concentrations.

7.1.1.2. Long-term toxicity to fish

No relevant information available.

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 7.2. Short-term effects on aquatic invertebrates

Method	Results	Remarks
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): 53 mg/L test mat. (meas. (geom. mean)) based on: mobility NOEC (48h): 46 mg/L test mat. (meas. (geom. mean)) based on: mobility	2 (reliable with restrictions) key study experimental study Test material Ruthenium (III) chloride hydrate, (full information in Annex II). Reference Enste-Diefenbach R 2003

Discussion

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

The 48h EC50 for ruthenium trichloride (hydrate) to Daphnia magna was 53 mg L-1.

Additional information:

Enste-Diefenbach (2003) is GLP compliant study and follows OECD guideline 202 and EU method C2. The study was conducted over 48 hours under static conditions. Test concentrations were analysed and results based on mean measured concentrations. There are limitations with the study as evidence of flocculants was observed in the test solutions after 48 hours and there were likely to have been pH effects at the highest test concentrations. The toxicity observed is therefore unlikely to be solely due to toxicity of the test item. The 48h EC50 for ruthenium trichloride (hydrate) to Daphnia magna was 53 mg L-1.

7.1.2.2. Long-term toxicity to aquatic invertebrates

No relevant information available.



7.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 7.3. Effects on algae and aquatic plants

Method	Results	Remarks
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]	EC50 (72h): 0.602 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95% confidence intervals: 0.531 - 0.708 mg/L) EC50 (72h): 0.244 mg/L test mat. (meas. (geom. mean)) based on: yield NOEC (72h): <0.184 mg/L test mat. (meas. (geom. mean)) based on: growth rate and yield EC10 (72h): 0.233 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95% confidence intervals: 0.206 - 0.259)	1 (reliable without restriction) key study experimental study Test material Ruthenium (III) chloride hydrate / 14898-67-0, Form: solid: particulate/powder - migrated information: powder (full information in Annex II). Reference Wenzel A 2018

Discussion

Effects on algae / cyanobacteria

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

The 72-h EC50 based on growth rate was 0.602 mg L⁻¹ and the EC10 was 0.233 mg L⁻¹. The 72-h EC50 based on yield was 0.244 mg L⁻¹ and the EC10 could not be determined. The NOEC for growth rate and yield was <0.184 mg L⁻¹.

Additional information:

A GLP- compliant 72-h algal growth inhibition study was conducted for ruthenium trichloride (hydrate) following OECD guideline 201 (Wenzel 2016).

Two pre-tests were conducted, followed by a definitive test with nominal concentrations of 1.25, 2.50, 5.00, 10.0 and 20.0 mg test item L⁻¹, prepared in sterile AAP growth medium. Test solutions were analysed for ruthenium using ICP-OES and mean measured concentrations of 0.268, 0.184, 0.219, 0.345 and 1.882 mg test item L⁻¹ used for reporting of results.

There were concentration-dependent effects on the growth of the green algae over the range of the tested concentrations. The 72-h EC50 based on growth rate was 0.602 mg L⁻¹ and the EC10 was 0.233 mg L⁻¹. The 72-h EC50 based on yield was 0.244 mg L⁻¹ and the EC10 could not be determined. The NOEC was calculated to be below the lowest test concentration of 0.184 mg 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. Atmospheric compartment

No relevant information available.

7.4. 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): 220 mg/L test mat. (nominal) based on: growth inhibition - Inhibition based on total respiration without ATU (--) NOEC (3h): 220 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration - with ATU (--) EC10 (3h): 360 mg/L test mat. (nominal) based on: growth inhibition - based on total respiration without ATU (95% Confidence Interval 310 - 400 mg/L) EC10 (3h): 230 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration - with ATU (95% Confidence Interval 230 - 240 mg/L) EC50 (3h): 530 mg/L test mat. (nominal) based on: growth inhibition - based on total respiration without ATU (95% Confidence Interval 480 - 580 mg/L) EC50 (3h): 330 mg/L test mat. (nominal) based on: inhibition of heterotrophic respiration - with ATU (95% Confidence Interval 320 - 340 mg/L)	1 (reliable without restriction) key study experimental study Test material Ruthenium (III) chloride hydrate, Form: solid: particulate/powder (full information in Annex II). Reference Muckle M 2016



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Discussion

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

The 3-h EC50 was 530 mg L⁻¹ (without ATU) and 330 mg L⁻¹ (with ATU). The EC10 was 360 mg L⁻¹ (without ATU) and 230 mg L⁻¹ (with ATU). The NOEC was 220 mg L⁻¹ both with and without ATU.

Additional information:

An activated sludge respiration inhibition test following OECD guideline 209 was conducted (Muckle 2016). The respiration rates of samples of activated sludge fed with synthetic sewage were measured in an enclosed cell containing an oxygen electrode after a contact time of 3 hours. The sensitivity of each batch of activated sludge was checked with a positive control (3,5-Dichlorophenol); all values were within the recommended range for the positive control.

In the first experiment, which was performed as the range finding test, the test item was tested using 4 concentrations ranging from 1 to 1000 mg L⁻¹ nominal concentration. Two test series using the same concentration were performed in order to discern between inhibition of nitrifiers and inhibition of the total population of heterotrophic bacteria. Therefore, the nitrification inhibitor N-allylthiourea (ATU) was added to all flasks for the second test series.

In the second experiment the test item was assessed using 5 concentrations ranging from 46 to 1000 mg L⁻¹ nominal concentration without ATU. The dry matter of the inoculum was determined as 2.80 g suspended solids/L, giving a concentration of 1.40 g suspended solids in the test. The fourth experiment was conducted with the same concentrations but with ATU.

The 3-h EC50 was 530 mg L⁻¹ (without ATU) and 330 mg L⁻¹ (with ATU). The EC10 was 360 mg L⁻¹ (without ATU) and 230 mg L⁻¹ (with ATU). The NOEC was 220 mg L⁻¹ both with and without ATU.

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

7.5.1. Toxicity to birds

No relevant information available.

7.5.2. Toxicity to mammals

No relevant information available.

7.6. PNEC derivation and other hazard conclusions

7.6.1. PNEC derivation and other hazard conclusions

Table 7.5. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 0.244 µg/L Intermittent releases: 2.44 µg/L	Assessment factor: 1000 Extrapolation method: assessment factor PNEC aqua (freshwater)



		The PNEC freshwater is derived based on a lowest EC50 of 0.244 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 0.244 mg Ru L-1 and an assessment factor of 100. For further details see attached PNEC report.
Marine water	PNEC aqua (marine water): 0.024µg/L Intermittent releases:	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 0.244 mg Ru L-1 and an assessment factor of 10000. For further details see attached PNEC report.
Sediments (freshwater)	PNEC sediment (freshwater): 7.62mg/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): 0.762mg/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: 8.92mg/L	Assessment factor: 10 Extrapolation method: assessment factor PNEC STP The PNEC STP is derived based on a NOEC of 89.2 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: 1.55mg/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 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 0.602 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. The algal NOEC is unbounded and therefore the EC₁₀ is used for classification purposes (0.233 mg test item L-1). 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 (*Raphidocelis 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

No relevant information available.

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



9. EXPOSURE ASSESSMENT (and related risk characterisation)

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

9.0. Introduction

9.0.1. Overview on uses

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

9.0.2. Assessment entity groups

Not applicable

9.0.3. Introduction to the assessment for the environment

9.0.3.1. Tonnage

Assessed tonnage: 55.23 tonnes/year based on:

- 55.23 tonnes/year manufactured

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

Table 9.1. Tonnage for assessment

ES#	Exposure scenario (ES) name and related environmental contributing scenarios	Tonnage per use (t/year)	Daily local tonnage (t/day)	Annual local tonnage (t/year)
ES1 (M)	Manufacture (of the substance as such)	48.73		
	- Manufacture (of the substance as such) - Discharge via STP (ERC 1)		0.148	48.73
	- Manufacture (of the substance as such) - Direct discharge (ERC 1)		0.148	48.73
ES2 (M)	Manufacture of the substance in the catalyst industry	6.5		
	- Manufacture of the substance in the catalyst industry (ERC 1)		0.016	6.5
ES3 (F)	Formulation of surface treatment solutions	1.75		
	- Formulation of surface treatment solutions (ERC 2)		5.3E-3	1.75
ES4 (IS)	Use in electroplating - Industrial	0.47		
	- Use in electroplating - Industrial (ERC 5)		2.14E-3	0.47
ES5 (IS)	Use as intermediate - industrial	48.73		
	- Use as intermediate - industrial with STP (ERC 6a)		0.148	48.73
	- Use as intermediate - industrial with direct discharge (ERC 6a)		0.148	48.73
ES6 (PW)	Use in electroplating - Professional	5.3E-3		
	- Use in electroplating - Professional (ERC 8c)		3.57E-5	-
ES7 (SL)	Service life of treated articles			
	- Service life of treated articles (ERC 10a)		-	-

9.0.3.2. Scope and type of assessment for the environment



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

Table 9.2. Type of risk characterisation required for the environment

Protection target	Risk characterisation type	Hazard conclusion (see section 7)
Fresh water	Quantitative	PNEC aqua (freshwater) = 0.244 µg/L
Sediment (freshwater)	Quantitative	PNEC sediment (freshwater) = 7.62 mg/kg sediment dw
Marine water	Quantitative	PNEC aqua (marine water) = 0.024 µg/L
Sediment (marine water)	Quantitative	PNEC sediment (marine water) = 0.762 mg/kg sediment dw
Sewage Treatment Plant	Quantitative	PNEC STP = 8.92 mg/L
Air	Not needed	No hazard identified
Agricultural soil	Quantitative	PNEC soil = 1.55 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
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	225.4 - 261.4
Molecular weight used for the assessment	261.4
Melting point at 101 325 Pa	450 °C
Vapour pressure	1E-12 Pa at 20 °C
Water solubility	1.14E3 g/L
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

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 .

Explanation:

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 partitioning to sewage sludge at STPs with the remaining 54% passing through the STP to the receiving water body.

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

9.0.3.4. Comments on assessment approach for the environment

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

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).

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 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'⁴ (0.04% or 400 g/T as Ru has a K_d 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.

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' 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.

Summary information gathered from the Ru industry:

Value	Site Tonnage (tpa Ruthenium trichloride)	Emission days per site (d/yr)	
		Water	Air
50P	-	333	365
Min	-	250	360
Max	100 (tonnage band max) ¹	365	365
n	4	4	4
Selected for Exposure Scenario	100 (tonnage band max)	330 (lowest 50P to 2 sig fig)	

¹ Equivalent to 48.73 tpa ruthenium metal



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 & 5.1 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 sector data)
Selected for ES 1.2 & 5.2 Freshwater – direct discharge to water		3000		1000 max (dilution factor for only site with direct discharge is 4800)		

In the absence of measured emissions data from downstream users of Ru compounds the approach involving the use of metal-specific release factors (as defined by SPERCs) was applied. Further refinements involved the adjustment of SpERC-defined release factors and the option remains to also introduce site-specific emission data, when available. Emissions of ruthenium, and ruthenium compounds, to water based on RFs taken from the SpERC documents have been adjusted to 10% of the recommended values (with the exception of adjustment to the wastewater RF for formulation which is discussed in ES 3 and use in electroplating professional (ES 6) where 10 % of the ERC value is used), RF factors to air are unadjusted. It is assumed that all downstream users of ruthenium trichloride will discharge wastewater emissions via an STP. For downstream user scenarios no dilution factor data were provided so the default STP flow rate and dilution factors of 10 for freshwater are applied.

Summary information for downstream use generic exposure scenarios:

GES	Wastewater discharge				Stack emissions to air	
	Release factor (g/T)	Emission days	STP flow rate (m ³ /d)	Receiving water flow rate (m ³ /d)	Release factor (g/T)	Emission days
ES 2 Manufacture of the substance in the catalyst industry	67 (10% SpERC RF)	280	2,000 (TGD default)	18,000 (TGD default)	250 (SpERC RF)	280
ES 3 Formulation of surface treatment solutions	200 (1% pre-WWTP SpERC RF)	330			100 (SpERC RF)	330
ES 4 Use in electroplating – Industrial	500 (10 % SpERC)	220			2000 (SpERC RF)	220
ES 6 Use in electroplating - professional	30000 (10 % ERC)	280			150000 (SpERC RF)	280



9.0.3.5. Scope and type of assessment for man via environment

The exposure assessment for man via environment is not needed.

An assessment of indirect exposure of humans via the environment is generally only conducted if:

- the tonnage >1 000 t/y or
- the tonnage >100 t/Y and the substance is classified as STOT RE 1; or as a carcinogen or mutagen (any category); or as toxic to reproduction (categories 1A or 1B). (Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 3.0, February 2016))

9.0.4. Introduction to the assessment for workers

9.0.4.1. Scope and type of assessment for workers

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

Table 9.4. Type of risk characterisation required for workers

Route	Type of effect	Risk characterisation type	Hazard conclusion (see section 5.11)
Inhalation	Systemic effects - long term	Quantitative	DNEL (Derived No Effect Level) = 0.38 mg/m ³
	Systemic effects - acute	Not needed	No hazard identified
	Local effects - long term	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	Qualitative	Medium hazard (no threshold derived)
Dermal	Systemic effects - long term	Quantitative	DNEL (Derived No Effect Level) = 0.27 mg/kg bw/day
	Systemic effects - acute	Not needed	No hazard identified
	Local effects - long term	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	Qualitative	Medium hazard (no threshold derived)
Eye	Local effects	Qualitative	Medium hazard (no threshold derived)

9.0.4.2. Comments on assessment approach for workers

Assessment approach related to toxicological hazard:

GENERAL GOOD OCCUPATIONAL HYGIENE PRACTICES

In the 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.

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.

General information on risk management related to physicochemical hazard:

Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMS will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern. The substance is classified as Metal corrosivity category 1 (H290), therefore do not handle until all safety precautions have been read and understood.

9.0.5. Introduction to the assessment for consumers

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



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

Environment contributing scenario(s):		
CS 1	Manufacture (of the substance as such) - Discharge via 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)	PROC 1
CS 4	Closed batch process (PROC 3)	PROC 3
CS 5	Open or semi-closed reaction process (PROC 4)	PROC 4
CS 6	Transfer of substance (charging/discharging) at non-dedicated facilities (PROC 8a)	PROC 8a
CS 7	Transfer of substance (charging/discharging) at non-dedicated facilities (PROC 8a)	PROC 8b
CS 8	Wet cleaning (PROC 8a)	PROC 8a
CS 9	Handling of solid inorganic substances at ambient temperature (PROC 26)	PROC 26
CS 10	Filling/handling/transfer of solutions (PROC 8b)	PROC 8b
CS 11	Transfer of substance into small containers (including weighing) (PROC 9)	PROC 9
CS 12	Small scale handling/transfer of solutions (PROC 9)	PROC 9
CS 13	Use as laboratory reagent (PROC 15)	PROC 15
CS 14	Laboratory analyses (PROC 15)	PROC 15
CS 15	Open processing at elevated temperature (PROC 23)	PROC 23
CS 16	Vacuum cleaning (PROC 26)	PROC 26

Further description of the use:

Mixtures of impure RuCl₃ Hydrate, and Ruthenates from recycling process are oxidized to Ruthenium tetroxide, which evaporates in gaseous form, due to bad solubility in aqueous solution. The distillate is absorbed in aqueous hydrochloric acid, where aquation and hydrolysis occurs. Resulting solution of RuCl₃ Hydrate is carefully evaporated to requested concentration or to the solid.

9.1.1. Env CS 1: Manufacture (of the substance as such) - Discharge via 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: ≤ 0.148 tonnes/day <i>Based on 330 days of processing per annum</i> - Annual use amount at site: ≤ 48.73 tonnes/year
Conditions and measures related to biological sewage treatment plant
- Biological STP: Site specific [Effectiveness Water: 46%] - Discharge rate of STP: ≥ 9.36E3 m³/day <i>10th percentile of measured data</i> - Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
Particular considerations on the waste treatment operations: No (low risk) <i>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</i>



waste landfills as hazardous waste. Releases 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: $\geq 4.59E5$ m ³ /day
• Discharge to: Freshwater only

Fate (release percentage) in the biological sewage treatment plant

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

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

Explanation:

Data from an STP monitoring program conducted at three STPs in Europe (1 in the UK, 2 in Germany)

9.1.1.2. Releases

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

Table 9.6. Local releases to the environment

Release	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: 5.91E-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: 0.044 kg/day
Non agricultural soil	Estimated release factor (Best practice)	Release factor after on site RMM: 0%

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

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

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

Protection target	Exposure concentration	Risk quantification
Fresh water	Local PEC: 5.16E-6 mg/L	RCR = 0.021
Sediment (freshwater)	Local PEC: 0.163 mg/kg dw	RCR = 0.021
Sewage Treatment Plant	Local PEC: 3.41E-4 mg/L	RCR < 0.01
Agricultural soil	Local PEC: 0.012 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: ≤ 0.148 tonnes/day <i>Based on 330 days of processing per annum</i>
• Annual use amount at site: ≤ 48.73 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)
• Particular considerations on the waste treatment operations: No (low risk) <i>Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the ruthenium content of the waste is elevated enough, internal or external recovery/recycling should be considered.</i> <i>Fraction of daily/annual use expected in waste: 0%</i> <i>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</i> <i>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%</i> <i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)</i>
Other conditions affecting environmental exposure
• Receiving surface water flow rate: $\geq 3E6$ m ³ /day
• Discharge rate of effluent: $\geq 3E3$ m ³ /day
• Discharge to: Freshwater only

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: 5.91E-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: 0.044 kg/day
Non agricultural soil	Estimated release factor (Best practice)	Release factor after on site RMM: 0%

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

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

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

Protection target	Exposure concentration	Risk quantification
Fresh water	Local PEC: 1.87E-6 mg/L	RCR < 0.01



Protection target	Exposure concentration	Risk quantification
Sediment (freshwater)	Local PEC: 0.059 mg/kg dw	RCR < 0.01
Agricultural soil	Local PEC: 0.012 mg/kg dw	RCR < 0.01

9.1.3. Worker CS 3: Process in fully contained system (PROC 1) (PROC 1)

9.1.3.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Maximum process temperature: 70 °C	
• Level of containment: Closed process	
• Dermal pattern of use: Wide dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.1.3.2. Exposure and risks for workers

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

Table 9.10. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026



Route of exposure and type of effects	Exposure concentration	Risk quantification
Dermal, systemic, long term	0.17 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.027

Remarks on exposure data from external estimation tools:**MEASE 1.02.01:**

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

Risk characterisation

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

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 CS 4: Closed batch process (PROC 3) (PROC 3)**9.1.4.1. Conditions of use**

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Level of containment: Closed process	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>Eye protection to be worn to protect from adverse effects to the eyes (moderate</i>	



	Method
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.)	

9.1.4.2. Exposure and risks for workers

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

Table 9.11. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.22 mg/m ³ (MEASE 1.02.01)	RCR = 0.579
Dermal, systemic, long term	0.17 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.58

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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 CS 5: Open or semi-closed reaction process (PROC 4) (PROC 4)

9.1.5.1. Conditions of use

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



	Method
Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] Standard efficiency Inhalation explanation: <i>Efficiency for industrial use</i>	
Dermal pattern of use: Non-dispersive use	
Dermal pattern of exposure control: Non-direct handling	
Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] 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.	
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%]	
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 (RCR) 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 quantification
Inhalation, systemic, long term	0.2 mg/m ³ (MEASE 1.02.01)	RCR = 0.526
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.528

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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 CS 6: Transfer of substance (charging/discharging) at non-dedicated facilities (PROC 8a) (PROC 8a)

Transfer of solid substance at non-dedicated facilities

9.1.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: 60 - 240 min [Effectiveness Inhalation: 40%, Dermal: 40%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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.</i>	

9.1.6.2. Exposure and risks for workers

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

Table 9.13. Exposure concentrations and risks for workers



Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.24 mg/m ³ (MEASE 1.02.01)	RCR = 0.632
Dermal, systemic, long term	41 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.152
Combined routes, systemic, long-term		RCR = 0.783

Remarks on exposure data from external estimation tools:**MEASE 1.02.01:**

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

Risk characterisation

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

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 CS 7: Transfer of substance (charging/discharging) at non-dedicated facilities (PROC 8a) (PROC 8b)

Transfer of solid substance at dedicated facilities

9.1.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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</i>	



	Method
EN 529 is required.	
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%]	
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.)	

9.1.7.2. Exposure and risks for workers

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

Table 9.14. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.2 mg/m ³ (MEASE 1.02.01)	RCR = 0.526
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.528

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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 CS 8: Wet cleaning (PROC 8a) (PROC 8a)

9.1.8.1. Conditions of use

	Method
Product (article) characteristics	
Physical form of substance: Solution	
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.	
Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation:	



	Method
0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.1.8.2. Exposure and risks for workers

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

Table 9.15. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.05 mg/m ³ (MEASE 1.02.01)	RCR = 0.132
Dermal, systemic, long term	34 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.126
Combined routes, systemic, long-term		RCR = 0.258

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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 CS 9: Handling of solid inorganic substances at ambient temperature (PROC 26) (PROC 26)



Handling of solid inorganic substances at ambient temperatures

9.1.9.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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.</i>	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	

9.1.9.2. Exposure and risks for workers

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

Table 9.16. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.08 mg/m ³ (MEASE 1.02.01)	RCR = 0.211
Dermal, systemic, long term	1.4 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01



Route of exposure and type of effects	Exposure concentration	Risk quantification
Combined routes, systemic, long-term		RCR = 0.216

Remarks on exposure data from external estimation tools:**MEASE 1.02.01:**

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

Risk characterisation

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

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.

9.1.10. Worker CS 10: Filling/handling/transfer of solutions (PROC 8b) (PROC 8b)

9.1.10.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>RPE protecting from local effects via inhalation (moderate hazard). (Due to potential</i>	



	Method
<i>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.)</i>	

9.1.10.2. Exposure and risks for workers

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

Table 9.17. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.028

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.1.11. Worker CS 11: Transfer of substance into small containers (including weighing) (PROC 9) (PROC 9)

Transfer of solid substance (including weighing)

9.1.11.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	



	Method
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] <i>APF = assigned protection factor according to EN 529. At minimum any combination of particle filter class P2 with mask according to EN 140, EN 1827 or EN 136 or filtering half mask (FF P2) according to EN 149 or combination of P1 filter with face piece according to EN 12942 or any RPE providing higher APFs according to EN 529 is required.</i>	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	

9.1.11.2. Exposure and risks for workers

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

Table 9.18. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.32 mg/m ³ (MEASE 1.02.01)	RCR = 0.842
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Combined routes, systemic, long-term		RCR = 0.855

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.1.12. Worker CS 12: Small scale handling/transfer of solutions (PROC 9) (PROC 9)

9.1.12.1. Conditions of use



	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	
• Respiratory protective equipment (RPE): RPE with minimum APF = 4 [Effectiveness Inhalation: 75%] <i>APF = assigned protection factor according to EN 529. At minimum any combination of particle filter class P1 with mask according to EN 140, EN 1827 or EN 136 or filtering half mask (FF P1) according to EN 149 or any RPE providing higher APFs according to EN 529 is required.</i>	

9.1.12.2. Exposure and risks for workers

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

Table 9.19. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Combined routes, systemic, long-term		RCR = 0.039

Remarks on exposure data from external estimation tools:

**MEASE 1.02.01:**

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

Risk characterisation

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

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.

9.1.13. Worker CS 13: Use as laboratory reagent (PROC 15) (PROC 15)

Use of solid as laboratory reagent

9.1.13.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] <i>APF = assigned protection factor according to EN 529. At minimum any combination of particle filter class P2 with mask according to EN 140, EN 1827 or EN 136 or filtering half mask (FF P2) according to EN 149 or combination of P1 filter with face piece according EN 12942 or any RPE providing higher APFs according to EN 529 is required.</i>	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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</i>	



	Method
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.)	

9.1.13.2. Exposure and risks for workers

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

Table 9.20. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.08 mg/m ³ (MEASE 1.02.01)	RCR = 0.211
Dermal, systemic, long term	1.7 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.217

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.1.14. Worker CS 14: Laboratory analyses (PROC 15) (PROC 15)

9.1.14.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>Due to the potential adverse effects of the substance to skin (moderate hazard),</i>	



	Method
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.)	

9.1.14.2. Exposure and risks for workers

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

Table 9.21. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	1.7 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.033

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.1.15. Worker CS 15: Open processing at elevated temperature (PROC 23) (PROC 23)

9.1.15.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.	



	Method
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Maximum process temperature: 450 °C <i>Elevated, but below melting point (i.e. < 450 °C)</i>	
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.1.15.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) 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 quantification
Inhalation, systemic, long term	0.11 mg/m ³ (MEASE 1.02.01)	RCR = 0.289
Dermal, systemic, long term	1.4 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.295

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term,



Dermal, local, acute, Eye, local):

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.

9.1.16. Worker CS 16: Vacuum cleaning (PROC 26) (PROC 26)

9.1.16.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner. Inhalation explanation: Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
• Additional operational conditions for cleaning: No direct manual removal of dust.	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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.</i>	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	

9.1.16.2. Exposure and risks for workers



The exposure concentrations and risk characterisation ratios (RCR) 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 quantification
Inhalation, systemic, long term	0.08 mg/m ³ (MEASE 1.02.01)	RCR = 0.211
Dermal, systemic, long term	1.4 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.216

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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: Manufacture - Manufacture of the substance in the catalyst industry

Environment contributing scenario(s):		
CS 1	Manufacture of the substance in the catalyst industry	ERC 1
Worker contributing scenario(s):		
CS 2	Fully contained process (PROC 1)	PROC 1
CS 3	Closed batch process (PROC 3)	PROC 3
CS 4	Filling/handling/transfer of solutions (PROC 8b)	PROC 8b
CS 5	Small scale handling/transfer of solutions (PROC 9)	PROC 9
CS 6	Potentially-closed processing at elevated temperature (PROC 22)	PROC 22
CS 7	Vacuum cleaning (PROC 26)	PROC 26
CS 8	Production of metal powders (wet processes) (PROC 27b)	PROC 27b

9.2.1. Env CS 1: Manufacture of the substance in the catalyst industry (ERC 1)

9.2.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: ≤ 0.016 tonnes/day <i>Based on SpERC emission days of 280 days per year</i>
• Annual use amount at site: ≤ 6.5 tonnes/year
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 46%]
• Discharge rate of STP: $\geq 2E3$ m ³ /day
• Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low risk) <i>Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the ruthenium content of the waste is elevated enough, internal or external recovery/recycling should be considered.</i> <i>Fraction of daily/annual use expected in waste: 0%</i> <i>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</i> <i>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%</i> <i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)</i>
Other conditions affecting environmental exposure
• Receiving surface water flow rate: $\geq 1.8E4$ m ³ /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%
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Explanation:

Data from an STP monitoring program conducted at three STPs in Europe (1 in the UK, 2 in Germany)

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 9.24. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor (10 % of SpERC)	Release factor before on site RMM: 6.7E-3% Release factor after on site RMM: 6.7E-3% Local release rate: 1.06E-3 kg/day
Air	Estimated release factor (SpERC)	Release factor before on site RMM: 0.025% Release factor after on site RMM: 0.025% Local release rate: 3.97E-3 kg/day
Non agricultural soil	Estimated release factor (Best practice)	Release factor after on site RMM: 0%

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

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

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

Protection target	Exposure concentration	Risk quantification
Fresh water	Local PEC: 2E-5 mg/L	RCR = 0.082
Sediment (freshwater)	Local PEC: 0.634 mg/kg dw	RCR = 0.083
Marine water	Local PEC: 2.02E-6 mg/L	RCR = 0.083
Sediment (marine water)	Local PEC: 0.064 mg/kg dw	RCR = 0.084
Sewage Treatment Plant	Local PEC: 2.88E-4 mg/L	RCR < 0.01
Agricultural soil	Local PEC: 7.17E-3 mg/kg dw	RCR < 0.01

9.2.2. Worker CS 2: Fully contained process (PROC 1) (PROC 1)

9.2.2.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Maximum process temperature: 70 °C	
• Level of containment: Closed process	



	Method
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.2.2.2. Exposure and risks for workers

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

Table 9.26. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	0.17 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.027

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.2.3. Worker CS 3: Closed batch process (PROC 3) (PROC 3)

9.2.3.1. Conditions of use

	Method
Product (article) characteristics	



	Method
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Level of containment: Closed process	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.2.3.2. Exposure and risks for workers

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

Table 9.27. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.22 mg/m ³ (MEASE 1.02.01)	RCR = 0.579
Dermal, systemic, long term	0.17 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.58

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:



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

Risk characterisation

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

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 CS 4: Filling/handling/transfer of solutions (PROC 8b) (PROC 8b)

9.2.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.2.4.2. Exposure and risks for workers

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

**Table 9.28. Exposure concentrations and risks for workers**

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.028

Remarks on exposure data from external estimation tools:**MEASE 1.02.01:**

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

Risk characterisation

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

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

9.2.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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</i>	



	Method
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.)	

9.2.5.2. Exposure and risks for workers

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

Table 9.29. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Combined routes, systemic, long-term		RCR = 0.039

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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 CS 6: Potentially-closed processing at elevated temperature (PROC 22) (PROC 22)

9.2.6.1. Conditions of use

	Method
Product (article) characteristics	
Physical form of substance: Solid	
Maximum emission potential of the substance: High Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.	
Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
Maximum process temperature: 450 °C Elevated, but below melting point (i.e. < 450 °C)	



	Method
Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
Dermal pattern of use: Non-dispersive use	
Dermal pattern of exposure control: Non-direct handling	
Dermal contact level: Incidental	
Conditions and measures related to personal protection, hygiene and health evaluation	
Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
Eye protection: <i>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.)</i>	
Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	
Respiratory protective equipment (RPE): RPE with minimum APF = 4 [Effectiveness Inhalation: 75%] <i>APF = assigned protection factor according to EN 529. At minimum any combination of particle filter class P1 with mask according to EN 140, EN 1827 or EN 136 or filtering half mask (FF P1) according to EN 149 or any RPE providing higher APFs according to EN 529 is required.</i>	

9.2.6.2. Exposure and risks for workers

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

Table 9.30. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.22 mg/m ³ (MEASE 1.02.01)	RCR = 0.579
Dermal, systemic, long term	1.4 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.584

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

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

9.2.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner.</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
• Additional operational conditions for cleaning: No direct manual removal of dust.	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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.</i>	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	

9.2.7.2. Exposure and risks for workers

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

Table 9.31. Exposure concentrations and risks for workers



Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.08 mg/m ³ (MEASE 1.02.01)	RCR = 0.211
Dermal, systemic, long term	1.4 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.216

Remarks on exposure data from external estimation tools:**MEASE 1.02.01:**

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

Risk characterisation

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

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 CS 8: Production of metal powders (wet processes) (PROC 27b) (PROC 27b)

9.2.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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</i>	



	Method
be worn.)	
Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.2.8.2. Exposure and risks for workers

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

Table 9.32. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.1 mg/m ³ (MEASE 1.02.01)	RCR = 0.263
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.264

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.



9.3. Exposure scenario 3: Formulation or re-packing - Formulation of surface treatment solutions

Product category formulated: PC 14: Metal surface treatment products

Environment contributing scenario(s):		
CS 1	Formulation of surface treatment solutions	ERC 2
Worker contributing scenario(s):		
CS 2	Closed batch process (PROC 3)	PROC 3
CS 3	Open or semi-closed reaction process (PROC 4)	PROC 4
CS 4	Small scale handling/transfer of solutions (PROC 9)	PROC 9
CS 5	Vacuum cleaning (PROC 26)	PROC 26
CS 6	Production of metal powders (wet processes) (PROC 27b)	PROC 27b

9.3.1. Env CS 1: Formulation of surface treatment solutions (ERC 2)

9.3.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
- Daily use amount at site: $\leq 5.3E-3$ tonnes/day <i>Based on 330 emission days per year</i> - Annual use amount at site: ≤ 1.75 tonnes/year
Conditions and measures related to biological sewage treatment plant
- Biological STP: Site specific [Effectiveness Water: 46%] - Discharge rate of STP: $\geq 2E3$ m³/day - Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
Particular considerations on the waste treatment operations: No (low risk) <i>Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the ruthenium content of the waste is elevated enough, internal or external recovery/recycling should be considered.</i> <i>Fraction of daily/annual use expected in waste: 0%</i> <i>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</i> <i>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%</i> <i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)</i>
Other conditions affecting environmental exposure
Receiving surface water flow rate: $\geq 1.8E4$ 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%

Explanation:

Data from an STP monitoring program conducted at three STPs in Europe (1 in the UK, 2 in Germany)



9.3.1.2. Releases

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

Table 9.33. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor (1 % of SpERC)	Release factor before on site RMM: 0.02% Release factor after on site RMM: 0.02% Local release rate: 1.06E-3 kg/day Explanation: This SpERC does not take into account on-site WWTP so an additional correction factor has been applied resulting in a corrected SpERC for WWTP + monetary value of Ru.
Air	Estimated release factor (SpERC)	Release factor before on site RMM: 0.01% Release factor after on site RMM: 0.01% Local release rate: 5.3E-4 kg/day
Non agricultural soil	Estimated release factor (Best practice)	Release factor after on site RMM: 0%

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

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

Table 9.34. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	Local PEC: 2E-5 mg/L	RCR = 0.082
Sediment (freshwater)	Local PEC: 0.631 mg/kg dw	RCR = 0.083
Marine water	Local PEC: 2.01E-6 mg/L	RCR = 0.082
Sediment (marine water)	Local PEC: 0.063 mg/kg dw	RCR = 0.083
Sewage Treatment Plant	Local PEC: 2.86E-4 mg/L	RCR < 0.01
Agricultural soil	Local PEC: 6.69E-3 mg/kg dw	RCR < 0.01

9.3.2. Worker CS 2: Closed batch process (PROC 3) (PROC 3)

9.3.2.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Level of containment: Closed process	



	Method
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.3.2.2. Exposure and risks for workers

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

Table 9.35. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	0.17 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.027

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.3.3. Worker CS 3: Open or semi-closed reaction process (PROC 4) (PROC 4)

9.3.3.1. Conditions of use



	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.3.3.2. Exposure and risks for workers

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

Table 9.36. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	50 µg/m ³ (MEASE 1.02.01)	RCR = 0.132
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.133

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term,



Dermal, local, acute, Eye, local):

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.

9.3.4. Worker CS 4: Small scale handling/transfer of solutions (PROC 9) (PROC 9)

9.3.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	
• Respiratory protective equipment (RPE): RPE with minimum APF = 4 [Effectiveness Inhalation: 75%] <i>APF = assigned protection factor according to EN 529. At minimum any combination of particle filter class P1 with mask according to EN 140, EN 1827 or EN 136 or filtering half mask (FF P1) according to EN 149 or any RPE providing higher APFs according to EN 529 is required.</i>	

9.3.4.2. Exposure and risks for workers



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

Table 9.37. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Combined routes, systemic, long-term		RCR = 0.039

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.3.5. Worker CS 5: Vacuum cleaning (PROC 26) (PROC 26)

9.3.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner.</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
• Additional operational conditions for cleaning: No direct manual removal of dust.	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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</i>	



	Method
according to EN 12941 or EN 12942 or any RPE providing higher APFs according to EN 529 is required.	
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%]	
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.)	

9.3.5.2. Exposure and risks for workers

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

Table 9.38. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.08 mg/m ³ (MEASE 1.02.01)	RCR = 0.211
Dermal, systemic, long term	1.4 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.216

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.3.6. Worker CS 6: Production of metal powders (wet processes) (PROC 27b) (PROC 27b)

9.3.6.1. Conditions of use

	Method
Product (article) characteristics	
Physical form of substance: Solution	
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.	
Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	



	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.3.6.2. Exposure and risks for workers

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

Table 9.39. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.1 mg/m ³ (MEASE 1.02.01)	RCR = 0.263
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.264

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.



9.4. Exposure scenario 4: Use at industrial sites - Use in electroplating - Industrial

Product category used: PC 14: Metal surface treatment products

Environment contributing scenario(s):		
CS 1	Use in electroplating - Industrial	ERC 5
Worker contributing scenario(s):		
CS 2	Closed continuous process with occasional controlled exposure (PROC 2)	PROC 2
CS 3	Open or semi-closed reaction process (PROC 4)	PROC 4
CS 4	Filling/handling/transfer of solutions (PROC 8b)	PROC 8b
CS 5	Small scale handling/transfer of solutions/suspensions (PROC 9)	PROC 9
CS 6	Treatment of articles by dipping and pouring (PROC 13)	PROC 13
CS 7	Hand mixing (PROC 19)	PROC 19

9.4.1. Env CS 1: Use in electroplating - Industrial (ERC 5)

9.4.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
- Daily use amount at site: $\leq 2.14E-3$ tonnes/day Based on SpERC value of 220 emission days per year - Annual use amount at site: ≤ 0.47 tonnes/year
Conditions and measures related to biological sewage treatment plant
- Biological STP: Site specific [Effectiveness Water: 46%] - Discharge rate of STP: $\geq 2E3$ m³/day - Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
Particular considerations on the waste treatment operations: No (low risk) Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the 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: $\geq 1.8E4$ 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%
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Explanation:

Data from an STP monitoring program conducted at three STPs in Europe (1 in the UK, 2 in Germany)

9.4.1.2. Releases

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

Table 9.40. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor (10 % of SpERC)	Release factor before on site RMM: 0.05% Release factor after on site RMM: 0.05% Local release rate: 1.07E-3 kg/day
Air	Estimated release factor (SpERC)	Release factor before on site RMM: 0.2% Release factor after on site RMM: 0.2% Local release rate: 4.27E-3 kg/day
Non agricultural soil	ERC	Release factor after on site RMM: 1%

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

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

Table 9.41. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	Local PEC: 2.01E-5 mg/L	RCR = 0.082
Sediment (freshwater)	Local PEC: 0.636 mg/kg dw	RCR = 0.083
Marine water	Local PEC: 2.02E-6 mg/L	RCR = 0.083
Sediment (marine water)	Local PEC: 0.064 mg/kg dw	RCR = 0.084
Sewage Treatment Plant	Local PEC: 2.88E-4 mg/L	RCR < 0.01
Agricultural soil	Local PEC: 6.94E-3 mg/kg dw	RCR < 0.01

9.4.2. Worker CS 2: Closed continuous process with occasional controlled exposure (PROC 2) (PROC 2)

9.4.2.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	



	Method
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
• Level of containment: Closed process	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.4.2.2. Exposure and risks for workers

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

Table 9.42. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	1 µg/m ³ (MEASE 1.02.01)	RCR < 0.01
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.4.3. Worker CS 3: Open or semi-closed reaction process (PROC 4) (PROC 4)

9.4.3.1. Conditions of use



	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.4.3.2. Exposure and risks for workers

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

Table 9.43. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	50 µg/m ³ (MEASE 1.02.01)	RCR = 0.132
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.133

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term,



Dermal, local, acute, Eye, local):

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.

9.4.4. Worker CS 4: Filling/handling/transfer of solutions (PROC 8b) (PROC 8b)

9.4.4.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.4.4.2. Exposure and risks for workers

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

Table 9.44. Exposure concentrations and risks for workers



Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.028

Remarks on exposure data from external estimation tools:**MEASE 1.02.01:**

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

Risk characterisation

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

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.

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

9.4.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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</i>	



	Method
be worn.)	
Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.4.5.2. Exposure and risks for workers

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

Table 9.45. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Combined routes, systemic, long-term		RCR = 0.039

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.4.6. Worker CS 6: Treatment of articles by dipping and pouring (PROC 13) (PROC 13)

9.4.6.1. Conditions of use

	Method
Product (article) characteristics	
Physical form of substance: Solution	
Maximum emission potential of the substance: Very low <i>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.</i>	
Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
Dermal pattern of use: Non-dispersive use	
Dermal pattern of exposure control: Direct handling	



	Method
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.4.6.2. Exposure and risks for workers

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

Table 9.46. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Combined routes, systemic, long-term		RCR = 0.039

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.4.7. Worker CS 7: Hand mixing (PROC 19) (PROC 19)

9.4.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low	



	Method
Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.4.7.2. Exposure and risks for workers

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

Table 9.47. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	50 µg/m ³ (MEASE 1.02.01)	RCR = 0.132
Dermal, systemic, long term	34 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.126
Combined routes, systemic, long-term		RCR = 0.258

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.



9.5. Exposure scenario 5: Use at industrial sites - Use as intermediate - industrial

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

Environment contributing scenario(s):		
CS 1	Use as intermediate - industrial with STP	ERC 6a
CS 2	Use as intermediate - industrial with direct discharge	ERC 6a
Worker contributing scenario(s):		
CS 3	Process in fully contained system (PROC 1)	PROC 1
CS 4	Closed batch process (PROC 3)	PROC 3
CS 5	Open or semi-closed reaction process (PROC 4)	PROC 4
CS 6	Mixing or blending in batch process (PROC 5)	PROC 5
CS 7	Transfer of substance (charging/discharging) at non-dedicated facilities (PROC 8a)	PROC 8a
CS 8	Transfer of substance (charging/discharging) at dedicated facilities (PROC 8b)	PROC 8b
CS 9	Wet cleaning (PROC 8a)	PROC 8a
CS 10	Handling of solid inorganic substances at ambient temperature (PROC 26)	PROC 26
CS 11	Filling/handling/transfer of solutions (PROC 8b)	PROC 8b
CS 12	Transfer of substance into small containers (including weighing) (PROC 9)	PROC 9
CS 13	Small scale handling/transfer of solutions (PROC 9)	PROC 9
CS 14	Use as laboratory reagent (PROC 15)	PROC 15
CS 15	Laboratory analyses (PROC 15)	PROC 15
CS 16	Vacuum cleaning (PROC 26)	PROC 26

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

9.5.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 0.148 tonnes/day
• Annual use amount at site: <= 48.73 tonnes/year
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 46%]
• Discharge rate of STP: >= 9.36E3 m3/day 10th percentile of measured data
• Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low risk) <i>Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the ruthenium content of the waste is elevated enough, internal or external recovery/recycling should be considered.</i> 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: $\geq 4.59\text{E}5$ 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%

Explanation:

Data from an STP monitoring program conducted at three STPs in Europe (1 in the UK, 2 in Germany)

9.5.1.2. Releases

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

Table 9.48. 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: 5.91E-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: 0.044 kg/day
Non agricultural soil	ERC	Release factor after on site RMM: 0.1%

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

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

Table 9.49. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	Local PEC: 5.16E-6 mg/L	RCR = 0.021
Sediment (freshwater)	Local PEC: 0.163 mg/kg dw	RCR = 0.021
Marine water	Local PEC: 2.38E-6 mg/L	RCR = 0.097
Sediment (marine water)	Local PEC: 0.075 mg/kg dw	RCR = 0.099
Sewage Treatment Plant	Local PEC: 3.41E-4 mg/L	RCR < 0.01
Agricultural soil	Local PEC: 0.012 mg/kg dw	RCR < 0.01

9.5.2. Env CS 2: Use as intermediate - industrial with direct discharge (ERC 6a)

9.5.2.1. Conditions of use



Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: ≤ 0.148 tonnes/day
• Annual use amount at site: ≤ 48.73 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)
• Particular considerations on the waste treatment operations: No (low risk) <i>Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the ruthenium content of the waste is elevated enough, internal or external recovery/recycling should be considered.</i> <i>Fraction of daily/annual use expected in waste: 0%</i> <i>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</i> <i>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%</i> <i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)</i>
Other conditions affecting environmental exposure
• Receiving surface water flow rate: $\geq 3E6$ m ³ /day
• Discharge rate of effluent: $\geq 3E3$ m ³ /day

9.5.2.2. 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 9.50. 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: 5.91E-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: 0.044 kg/day
Non agricultural soil	ERC	Release factor after on site RMM: 0.1%

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

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

Table 9.51. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	Local PEC: 1.87E-6 mg/L	RCR < 0.01
Sediment (freshwater)	Local PEC: 0.059 mg/kg dw	RCR < 0.01
Agricultural soil	Local PEC: 0.012 mg/kg dw	RCR < 0.01

9.5.3. Worker CS 3: Process in fully contained system (PROC 1) (PROC 1)

9.5.3.1. Conditions of use



	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Maximum process temperature: 70 °C	
• Level of containment: Closed process	
• Dermal pattern of use: Closed system without breaches	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: None	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.5.3.2. Exposure and risks for workers

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

Table 9.52. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	0.17 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.027

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

**Risk characterisation**

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

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.

9.5.4. Worker CS 4: Closed batch process (PROC 3) (PROC 3)**9.5.4.1. Conditions of use**

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Level of containment: Closed process	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.5.4.2. Exposure and risks for workers



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

Table 9.53. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.22 mg/m ³ (MEASE 1.02.01)	RCR = 0.579
Dermal, systemic, long term	0.17 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.58

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

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

9.5.5.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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</i>	



	Method
according to EN 12941 or EN 12942 or any RPE providing higher APFs according to EN 529 is required.	
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%]	
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.)	

9.5.5.2. Exposure and risks for workers

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

Table 9.54. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.2 mg/m ³ (MEASE 1.02.01)	RCR = 0.526
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.528

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.5.6. Worker CS 6: Mixing or blending in batch process (PROC 5) (PROC 5)

9.5.6.1. Conditions of use

	Method
Product (article) characteristics	
Physical form of substance: Solid	
Maximum emission potential of the substance: High Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.	
Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	



	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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.</i>	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	

9.5.6.2. Exposure and risks for workers

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

Table 9.55. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.2 mg/m ³ (MEASE 1.02.01)	RCR = 0.526
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.528

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.5.7. Worker CS 7: Transfer of substance (charging/discharging) at non-dedicated facilities (PROC 8a) (PROC 8a)

Transfer of solid substance at non-dedicated facilities

9.5.7.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: 60 - 240 min [Effectiveness Inhalation: 40%, Dermal: 40%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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.</i>	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	

9.5.7.2. Exposure and risks for workers



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

Table 9.56. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.24 mg/m ³ (MEASE 1.02.01)	RCR = 0.632
Inhalation, local, long term	0.24 mg/m ³ (MEASE 1.02.01)	Qualitative risk
Dermal, systemic, long term	41 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.152
Dermal, local, long term	3 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Dermal, local, acute	3 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Combined routes, systemic, long-term		RCR = 0.783

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.5.8. Worker CS 8: Transfer of substance (charging/discharging) at dedicated facilities (PROC 8b) (PROC 8b)

Transfer of solid substance at dedicated facilities

9.5.8.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	



	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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.</i>	
Gloves/face protection: <i>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%]</i>	
Eye protection: <i>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.)</i>	

9.5.8.2. Exposure and risks for workers

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

Table 9.57. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.2 mg/m ³ (MEASE 1.02.01)	RCR = 0.526
Inhalation, local, long term	0.2 mg/m ³ (MEASE 1.02.01)	Qualitative risk
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Dermal, local, long term	0.05 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Dermal, local, acute	0.05 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Combined routes, systemic, long-term		RCR = 0.528

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

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

9.5.9.1. Conditions of use



	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.5.9.2. Exposure and risks for workers

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

Table 9.58. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	50 µg/m ³ (MEASE 1.02.01)	RCR = 0.132
Dermal, systemic, long term	34 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.126
Combined routes, systemic, long-term		RCR = 0.258

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

Qualitative risk characterisation (Inhalation, local, long term, Inhalation, local, acute, Dermal, local, long term,



Dermal, local, acute, Eye, local):

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.

9.5.10. Worker CS 10: Handling of solid inorganic substances at ambient temperature (PROC 26) (PROC 26)

Handling of solid inorganic substances at ambient temperatures

9.5.10.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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.</i>	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	



9.5.10.2. Exposure and risks for workers

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

Table 9.59. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.08 mg/m ³ (MEASE 1.02.01)	RCR = 0.211
Inhalation, local, long term	0.08 mg/m ³ (MEASE 1.02.01)	Qualitative risk
Dermal, systemic, long term	1.4 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Dermal, local, long term	0.05 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Dermal, local, acute	0.05 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Combined routes, systemic, long-term		RCR = 0.216

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.5.11. Worker CS 11: Filling/handling/transfer of solutions (PROC 8b) (PROC 8b)

9.5.11.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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,</i>	



	Method
<i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.5.11.2. Exposure and risks for workers

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

Table 9.60. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.028

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.5.12. Worker CS 12: Transfer of substance into small containers (including weighing) (PROC 9) (PROC 9)

Transfer of solid substance (including weighing)

9.5.12.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	



	Method
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] <i>APF = assigned protection factor according to EN 529. At minimum any combination of particle filter class P2 with mask according to EN 140, EN 1827 or EN 136 or filtering half mask (FF P2) according to EN 149 or combination of P1 filter with face piece according EN 12942 or any RPE providing higher APFs according to EN 529 is required.</i>	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	

9.5.12.2. Exposure and risks for workers

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

Table 9.61. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.32 mg/m ³ (MEASE 1.02.01)	RCR = 0.842
Inhalation, local, long term	0.32 mg/m ³ (MEASE 1.02.01)	Qualitative risk
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Dermal, local, long term	0.5 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Dermal, local, acute	0.5 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Combined routes, systemic, long-term		RCR = 0.855

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

Explanation: For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in



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

Risk characterisation

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

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.

9.5.13. Worker CS 13: Small scale handling/transfer of solutions (PROC 9) (PROC 9)

9.5.13.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.5.13.2. Exposure and risks for workers

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

Table 9.62. Exposure concentrations and risks for workers



Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Combined routes, systemic, long-term		RCR = 0.039

Remarks on exposure data from external estimation tools:**MEASE 1.02.01:**

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

Risk characterisation

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

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.

9.5.14. Worker CS 14: Use as laboratory reagent (PROC 15) (PROC 15)

Use of solid as laboratory reagent

9.5.14.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solid	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] <i>APF = assigned protection factor according to EN 529. At minimum any combination of particle filter class P2 with mask according to EN 140, EN 1827 or EN 136 or filtering half mask (FF P2) according to EN 149 or combination of P1 filter with face piece according EN 12942 or any RPE providing higher APFs according to EN 529 is required.</i>	



	Method
Gloves/face protection: <i>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%]</i>	
Eye protection: <i>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.)</i>	

9.5.14.2. Exposure and risks for workers

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

Table 9.63. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.08 mg/m ³ (MEASE 1.02.01)	RCR = 0.211
Inhalation, local, long term	0.08 mg/m ³ (MEASE 1.02.01)	Qualitative risk
Dermal, systemic, long term	1.7 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Dermal, local, long term	0.5 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Dermal, local, acute	0.5 µg/cm ² (MEASE 1.02.01)	Qualitative risk
Combined routes, systemic, long-term		RCR = 0.217

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.5.15. Worker CS 15: Laboratory analyses (PROC 15) (PROC 15)

9.5.15.1. Conditions of use

	Method
Product (article) characteristics	
Physical form of substance: Solution	
Maximum emission potential of the substance: Very low <i>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.</i>	
Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	



	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	
• Respiratory protective equipment (RPE) as precautionary measure: <i>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.)</i>	

9.5.15.2. Exposure and risks for workers

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

Table 9.64. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	10 µg/m ³ (MEASE 1.02.01)	RCR = 0.026
Dermal, systemic, long term	1.7 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.033

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.5.16. Worker CS 16: Vacuum cleaning (PROC 26) (PROC 26)

**9.5.16.1. Conditions of use**

	Method
Product (article) characteristics	
• Physical form of substance: Solid, powder / dust	
• Maximum emission potential of the substance: High <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] <i>Standard efficiency surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner.</i> Inhalation explanation: <i>Efficiency for industrial use</i>	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Extensive	
• Additional operational conditions for cleaning: No direct manual removal of dust.	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment (RPE): RPE with minimum APF = 20 [Effectiveness Inhalation: 95%] <i>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.</i>	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	
• Eye protection: <i>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.)</i>	

9.5.16.2. Exposure and risks for workers

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

Table 9.65. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.08 mg/m ³ (MEASE 1.02.01)	RCR = 0.211
Dermal, systemic, long term	1.4 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01



Route of exposure and type of effects	Exposure concentration	Risk quantification
Combined routes, systemic, long-term		RCR = 0.216

Remarks on exposure data from external estimation tools:**MEASE 1.02.01:**

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

Risk characterisation

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

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.



9.6. Exposure scenario 6: Widespread use by professional workers - Use in electroplating - Professional

Product category used: PC 14: Metal surface treatment products

Environment contributing scenario(s):		
CS 1	Use in electroplating - Professional	ERC 8c
Worker contributing scenario(s):		
CS 2	Closed continuous process with occasional controlled exposure (PROC 2)	PROC 2
CS 3	Open or semi-closed reaction process (PROC 4)	PROC 4
CS 4	Small scale handling/transfer of solutions/suspensions (PROC 9)	PROC 9
CS 5	Treatment of articles by dipping and pouring (PROC 13)	PROC 13
CS 6	Hand mixing (PROC 19)	PROC 19

9.6.1. Env CS 1: Use in electroplating - Professional (ERC 8c)

9.6.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
- Daily local widespread use amount: $\leq 3.57\text{E-}5$ tonnes/day <i>Based on 280 emission days per year</i> - Percentage of EU tonnage used at regional scale: = 10 %
Conditions and measures related to biological sewage treatment plant
Biological STP: Standard [Effectiveness Water: 46%]
Conditions and measures related to external treatment of waste (including article waste)
Particular considerations on the waste treatment operations: No (low risk) <i>Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the ruthenium content of the waste is elevated enough, internal or external recovery/recycling should be considered.</i> <i>Fraction of daily/annual use expected in waste: 0%</i> <i>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</i> <i>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%</i> <i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2017)</i>

9.6.1.2. 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 9.66. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor (10 % of ERC)	Release factor before on site RMM: 3% Release factor after on site RMM: 3% Local release rate: 1.07E-3 kg/day
Air	Estimated release factor (10 % of ERC)	Release factor before on site RMM: 1.5% Release factor after on site RMM: 1.5%
Non agricultural	ERC	Release factor after on site RMM: 0%



Release	Release estimation method	Explanations
soil		

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

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

Table 9.67. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	Local PEC: 2.02E-5 mg/L	RCR = 0.083
Sediment (freshwater)	Local PEC: 0.637 mg/kg dw	RCR = 0.084
Marine water	Local PEC: 2.03E-6 mg/L	RCR = 0.083
Sediment (marine water)	Local PEC: 0.064 mg/kg dw	RCR = 0.084
Sewage Treatment Plant	Local PEC: 2.89E-4 mg/L	RCR < 0.01
Agricultural soil	Local PEC: 0.017 mg/kg dw	RCR = 0.011

9.6.2. Worker CS 2: Closed continuous process with occasional controlled exposure (PROC 2) (PROC 2)

9.6.2.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
• Level of containment: Closed process	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	



9.6.2.2. Exposure and risks for workers

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

Table 9.68. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	1 µg/m ³ (MEASE 1.02.01)	RCR < 0.01
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR < 0.01

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.6.3. Worker CS 3: Open or semi-closed reaction process (PROC 4) (PROC 4)

9.6.3.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	
• Maximum emission potential of the substance: Very low <i>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.</i>	
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Non-direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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.</i> [Effectiveness Dermal: 90%]	



	Method
Eye protection: <i>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.)</i>	

9.6.3.2. Exposure and risks for workers

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

Table 9.69. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.1 mg/m ³ (MEASE 1.02.01)	RCR = 0.263
Dermal, systemic, long term	0.34 µg/kg bw/day (MEASE 1.02.01)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.264

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.6.4. Worker CS 4: Small scale handling/transfer of solutions/suspensions (PROC 9) (PROC 9)

9.6.4.1. Conditions of use

	Method
Product (article) characteristics	
Physical form of substance: Solution	
Maximum emission potential of the substance: Very low <i>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.</i>	
Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
Dermal pattern of use: Non-dispersive use	
Dermal pattern of exposure control: Direct handling	
Dermal contact level: Intermittent	



	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
Gloves/face protection: <i>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%]</i>	
Eye protection: <i>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.)</i>	

9.6.4.2. Exposure and risks for workers

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

Table 9.70. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	50 µg/m ³ (MEASE 1.02.01)	RCR = 0.132
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Combined routes, systemic, long-term		RCR = 0.144

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.6.5. Worker CS 5: Treatment of articles by dipping and pouring (PROC 13) (PROC 13)

9.6.5.1. Conditions of use

	Method
Product (article) characteristics	
Physical form of substance: Solution	
Maximum emission potential of the substance: Very low <i>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.</i>	
Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	



	Method
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Dermal pattern of use: Non-dispersive use	
• Dermal pattern of exposure control: Direct handling	
• Dermal contact level: Intermittent	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves/face protection: <i>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%]</i>	
• Eye protection: <i>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.)</i>	

9.6.5.2. Exposure and risks for workers

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

Table 9.71. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	50 µg/m ³ (MEASE 1.02.01)	RCR = 0.132
Dermal, systemic, long term	3.4 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.013
Combined routes, systemic, long-term		RCR = 0.144

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.

9.6.6. Worker CS 6: Hand mixing (PROC 19) (PROC 19)

9.6.6.1. Conditions of use

	Method
Product (article) characteristics	
• Physical form of substance: Solution	



	Method
Maximum emission potential of the substance: Very low <i>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.</i>	
Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	
Amount used (or contained in articles), frequency and duration of use/exposure	
Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
Dermal pattern of use: Non-dispersive use	
Dermal pattern of exposure control: Direct handling	
Dermal contact level: Extensive	
Conditions and measures related to personal protection, hygiene and health evaluation	
Gloves/face protection: <i>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%]</i>	
Eye protection: <i>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.)</i>	

9.6.6.2. Exposure and risks for workers

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

Table 9.72. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	50 µg/m ³ (MEASE 1.02.01)	RCR = 0.132
Dermal, systemic, long term	34 µg/kg bw/day (MEASE 1.02.01)	RCR = 0.126
Combined routes, systemic, long-term		RCR = 0.258

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:

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

Risk characterisation

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

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.



9.7. Exposure scenario 7: Service life (consumers) - Service life of treated articles

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

Further description of the use:

Treated articles do not contain ruthenium trichloride but ruthenium in metallic form.

Explanation on the approach taken for the ES:

Ruthenium is a non hazardous substance for which exposure scenarios are not required.



10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

This chapter describes why a separate risk characterisation related to combined exposure is not required. Combined exposure may result from any of the following scenarios: 1. Multiple 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.

10.1.2. Consumer

Not relevant.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

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

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



Release route	Total releases per year
Water	5.078 kg/year
Air	32.05 kg/year
Soil	53.43 kg/year

10.2.2. Regional assessment

The regional predicted environmental concentration (PEC regional) and the related risk characterisation ratios when a PNEC is available are presented in the table below. The exposure to man via the environment from regional exposure and the related risk characterisation ratios are also provided (when relevant). The exposure concentration for human via inhalation is equal to the PEC air.

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

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

Protection target	Regional PEC	Risk characterisation
Fresh water	Regional PEC: 5.35E-7 mg/L	RCR < 0.01
Sediment (freshwater)	Regional PEC: 0.034 mg/kg dw	RCR < 0.01
Marine water	Regional PEC: 6.5E-8 mg/L	RCR < 0.01
Sediment (marine water)	Regional PEC: 4.11E-3 mg/kg dw	RCR < 0.01
Agricultural soil	Regional PEC: 6.63E-3 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.



Annexes



1. Annex: References

Ciffroy P., Durrieu G., Garnier J-M. 2009: Probabilistic distribution coefficients (K_{ds}) in freshwater for radioisotopes of Ag, Am, Ba, Be, Ce, Co, Cs, I, Mn, Pu, Ra, Ru, Sb, Sr and Th - implications for uncertainty analysis of models simulating the transport of radionuclides in rivers (publication), Journal of environmental radioactivity 100 (2009) 785 - 794.

Berthold K 1993: Ruthenium(III) chloride hydrate. Acute toxicity. Testing the acute toxicity after single oral administration in rats. (study report), Testing laboratory: ASTA Medica AG, Institute of Toxicology, Kantstrasse 2, D-33790 Halle/Westfalen, Report no: 894385. Owner company; Sponsor: Degussa AG/ZN Wolfgang, Industrielle Toxikologie (US-IT), Rodenbacher Chaussee 4, D-63457 Hanau, Study number: 93-0008-DGT, Report date: Sep 30, 1993

Lehmeier D 2013: In vitro skin corrosion: Membrane barrier test with ruthenium trichloride hydrate - solid (study report), Testing laboratory: BSL Bioservice, Scientific Laboratories GmbH, Behringstrasse 6/8, 82152 Planegg, Germany, Report no: 131985B. Owner company; Precious metals and Rhenium Consortium, c/o EPMF aisbl, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Aug 4, 2013

Lehmeier D 2013: In vitro skin corrosion: membrane barrier test with ruthenium trichloride, solution (study report), Testing laboratory: BSL Bioservice, Scientific Laboratories GmbH, Behringstrasse 6/8, 82152 Planegg, Germany, Report no: 131985C. Owner company; Precious Metals and Rhenium Consortium c/o EPMF aisbl, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Aug 4, 2013

Zelenák V 2017: Ruthenium Chloride: A 28-Day Dietary Toxicity Study in Wistar Rats With 14-Days Recovery (study report), Testing laboratory: CiToxLab Hungary, H-8200 Veszprém, Szabadságpuszta, Hungary., Report no: 15/266-100P. Owner company; The Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation Avenue de Broqueville 12 B-1150 Brussels, Belgium, Report date: Mar 1, 2017

McGarry S 2016: Ruthenium (III) chloride hydrate: Bacterial Reverse Mutation Assay (study report), Testing laboratory: Covance Laboratories Ltd. Otley Road, Harrogate North Yorkshire, HG3 1PY England, Report no: 8325448. Owner company; Precious Metals and Rhenium Consortium Avenue de Broqueville 12 B-1150 Brussels BELGIUM, Report date: Feb 3, 2016

Lloyd M 2016: Ruthenium (III) chloride hydrate: In vitro L5178Y Gene Mutation Assay at the hprt locus (study report), Testing laboratory: Covance Laboratories Ltd., Otley Road, Harrogate, North Yorkshire, HG3 1PY, England, Report no: 8325452. Owner company; Precious Metals and Rhenium Consortium, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: May 15, 2016

Lloyd M 2016: Ruthenium (III) chloride hydrate: In Vitro Human Lymphocyte Micronucleus Assay (study report), Testing laboratory: Covance Laboratories Ltd. Otley Road, Harrogate North Yorkshire, HG3 1PY, England, Report no: 8325450. Owner company; Precious Metals and Rhenium Consortium, Avenue de Broqueville 12, B-1150 Brussels, BELGIUM, Report date: Feb 2, 2016

Hargitai J 2017: Ruthenium Chloride: Reproduction/Developmental Toxicity Screening Test by Dietary Administration in Wistar Rats (study report), Testing laboratory: CiToxLAB Hungary Ltd., H-8200 Veszprém, Szabadságpuszta, Hungary, Report no: 15/266-209P. Owner company; The Precious Metals and Rhenium Consortium (REACH Consortium) c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Apr 28, 2017

Walker JA, White DF 2011: Ruthenium trichloride (hydrated solid): Determination of Physico-Chemical Properties (study report), Testing laboratory: Harlan Laboratories Ltd., Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK, Report no: Project Number 41003692. Owner company; Precious Metals and Rhenium Consortium (PMC), c/o EPMF, Report date: May 9, 2011

Atwal SS, Tremain SP 2011: Rhodium triiodide: Determination of Physico-Chemical Properties (study report), Testing laboratory: Harlan Laboratories Ltd, Shardlow Business Park, Shardlow, Derbyshire, DE2 2GD, Report no: 41003680. Owner company; Precious Metals and Rhenium Consortium (PMC) c/op European Precious Metals Federation Avenue de Broqueville 12 B-1150 Brussels, Belgium, Study number: Not reported, Report date: May 8, 2011



Muth-Köhne E. 2016: Fish acute toxicity test over 96 h under semi-static conditions (OECD TG 203, 1992) with zebrafish (*Danio rerio*), Test item: Ruthenium (III) chloride hydrate (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology IME, Auf dem Aberg 1, 57392 Schmallenberg, Germany, Report no: WCA-009/4-32/A. Owner company; Precious Metals and Rhenium Consortium, c/o European Precious Metals Federation, Avenue de Broqueville 12, B-1150 Brussels, Belgium, Report date: Oct 12, 2016

Enste-Diefenbach R 2003: Final Report DK 813 Ruthenium (III) chloride-hydrate Determination of the immobilisation of *Daphnia magna* STRAUS (study report), Testing laboratory: Infracor GmbH Analytical Technical Services Biology Building 9015/PB 10 Paul-Baumann-Str. 1 D-45764 Marl, Report no: DK-813. Owner company; OMG OM Group PC-RP-PS K. -H Krebs POBox 13 51 Rodenbacher-Chaussee 4 D-63457 Hanau-Wolfgang, Study number: Not reported, Report date: Nov 24, 2003

Wenzel A 2018: Freshwater Alga, Growth Inhibition Test (OECD 201) Tetraamminepalladium(2+) dichloride (CAS 13815-17-3): Effects on *Raphidocelis subcapitata* (study report), Testing laboratory: Fraunhofer Institute for Molecular Biology and Applied Ecology IME, Auf dem Aberg 1, 57392 Schmallenberg, Germany, Owner company; European Precious Metals Federation a.i.s.b.l., Avenue de Broqueville 12, B-1150 Brussels,, Belgium, Study number: EPM-001/4-10/A, Report date: Aug 21, 2018

Muckle M 2016: Determination of the inhibition of the respiration of activated sludge when exposed to ruthenium (III) chloride hydrate according to OECD 209 resp. EU C.11 (study report), Testing laboratory: LAUS GmbH, Auf der Schafweide, 20 D-67489 Kirrweiler, Germany, Report no: AB15100913G701. Owner company; Precious metals and rhenium consortium c/o EPMF, Study number: 15100913G701, Report date: Mar 22, 2016



2. Annex: Information on Test Material

Test material: **Ruthenium**

Form:

Composition type: Constituent	Reference substance: ruthenium EC no.: 231-127-1 CAS no: 7440-18-8 IUPAC name: ruthenium(2+)	Concentration range:
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Test material: **14898-67-0 / 14898-67-0 / 604-667-4; Rutheniumchloride hydrate**

Form:

Composition type: Constituent	Reference substance: Rutheniumchloride hydrate EC no.: CAS no: IUPAC name: Rutheniumchloride hydrate	Concentration range:
Composition type: Constituent	Reference substance: 14898-67-0 EC no.: 604-667-4 CAS no: 14898-67-0 IUPAC name: 14898-67-0	Concentration range:

Details on test material: - Name of test material (as cited in study report): Ruthenium(III) chloride hydrate - Substance type: Brown crystals - Physical state: Solid - Analytical purity: Metal used for the production of test substance was 99.9% pure - Impurities (identity and concentrations): No data - Composition of test material, percentage of components: No data - Isomers composition: No data - Purity test date: No data - Lot/batch No.: 8089/3-07/92 - Expiration date of the lot/batch: Jul-1997 - Stability under test conditions: Stable - Storage condition of test material: Dry in a closed container in a refrigerator - Other: - Solubility: soluble in water - pH: 1

Test material: **10049-08-8 / 233-167-5; 14898-67-0 / 14898-67-0 / 604-667-4**

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

Composition type: Constituent	Reference substance: 14898-67-0 EC no.: 604-667-4 CAS no: 14898-67-0 IUPAC name: 14898-67-0	Concentration range:
Composition type: Constituent	Reference substance: ruthenium trichloride EC no.: 233-167-5 CAS no: 10049-08-8 IUPAC name:	Concentration range:

Details on test material: - Name of test material (as cited in study report): Ruthenium trichloride hydrate - solid - Physical state: Dark brown solid - Analytical purity: Not specified. - Impurities (identity (concentration in ppm)): Rh (<30), Pd (<15), Ir (<40), Pt (<40), Os (<30), Al (<20), Ca (<10), Mg (<20), Si (33), Cu (<20), K (<20), Na (<10), Fe (<20). - Composition of test material, percentage of components: Ruthenium content 40.82% w/w - Isomers composition: Not specified. - Purity test date: Not specified. - Lot/batch No.: 11312 - Expiration date of the lot/batch: 31 December 2015 - Stability under test conditions: Not specified. - Storage condition of test material: Room temperature.

Test material: **10049-08-8 / 233-167-5; 14898-67-0 / 14898-67-0 / 604-667-4**

Form: **solution**

Composition type: Constituent	Reference substance: 14898-67-0 EC no.: 604-667-4 CAS no: 14898-67-0 IUPAC name: 14898-67-0	Concentration range:
Composition type: Constituent	Reference substance: ruthenium trichloride EC no.: 233-167-5	Concentration range:



	CAS no: 10049-08-8 IUPAC name:	
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Details on test material: - Name of test material (as cited in study report): Ruthenium trichloride, solution - Physical state: Brown liquid - Analytical purity: Not specified. - Impurities (identity (concentrations in ppm)): Rh (<30), Pd (<15), Ir (<40), Pt (<40), Os (55), Cu (<20), Fe (<20), Na (<10), K (<10), Ca (<10), Al (<20), Si (<30), Mg (<20). - Composition of test material, percentage of components: Ruthenium content 23.10% w/v - Isomers composition: Not specified. - Purity test date: Not specified. - Lot/batch No.: 13412 - Expiration date of the lot/batch: 31 December 2015 - Stability under test conditions: Not specified. - Storage condition of test material: Room temperature.

Test material: **Ruthenium (III) chloride hydrate**

Form: **solid: particulate/powder**

Composition type: Constituent	Reference substance: Ruthenium (III) chloride hydrate EC no.: CAS no: IUPAC name: Ruthenium (III) chloride hydrate	Concentration range:
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Test material: **Ruthenium (III) chloride hydrate / 14898-67-0**

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

Composition type: Constituent	Reference substance: Ruthenium trichloride hydrate EC no.: 604-667-4 CAS no: 14898-67-0 IUPAC name: Ruthenium trichloride hydrate	Concentration range:
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Test material: **14898-67-0 / 14898-67-0 / 604-667-4; Ruthenium (III) chloride hydrate**

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

Composition type: Constituent	Reference substance: Ruthenium (III) chloride hydrate EC no.: CAS no: IUPAC name: Ruthenium (III) chloride hydrate	Concentration range:
Composition type: Constituent	Reference substance: 14898-67-0 EC no.: 604-667-4 CAS no: 14898-67-0 IUPAC name: 14898-67-0	Concentration range:

Details on test material: - Name of test material (as cited in study report): Ruthenium (III) chloride hydrate - Substance type: No data. - Physical state: Dark brown powder. - Analytical purity: Assumed 100%. - Impurities (identity and concentrations (ppm)): Rh (<30), Pd (<15), Ir (<40), Pt (<40), Os (<30), Al (<20), Ca (<10), Mg (<20), Si (33), Cu (<20), K (29), Na (11), Fe (<20). Insolubles < 0.02% w/w. - Composition of test material, percentage of components: Ruthenium content 40.56% w/w. - Isomers composition: No data. - Purity test date: 16 June 2015. - Lot/batch No.: 89700002/10715 - Expiration date of the lot/batch: 15 June 2016 - Stability under test conditions: No data. - Storage condition of test material: Stored at 15-25degC, protected from light.

Test material: **14898-67-0 / 14898-67-0 / 604-667-4; Ruthenium (III) chloride hydrate**

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

Composition type: Constituent	Reference substance: Ruthenium (III) chloride hydrate EC no.: CAS no: IUPAC name: Ruthenium (III) chloride hydrate	Concentration range:
Composition type:	Reference substance: 14898-67-0	Concentration range:



Ruthenium trichloride (hydrate)

Constituent	EC no.: 604-667-4 CAS no: 14898-67-0 IUPAC name: 14898-67-0	
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Details on test material: - Name of test material (as cited in study report): Ruthenium (III) chloride hydrate - Substance type: dark brown powder - Physical state: solid - Analytical purity: ruthenium 40.56% - Impurities (identity and concentrations): Rh, <30 ppm; Pd, <15 ppm; Ir, <40 ppm; Pt, <40 ppm; Os, <30 ppm; Al, <20 ppm; Ca, <10 ppm; Mg, <20 ppm; Si, 33 ppm; Cu, <20 ppm; K, 29 ppm; Na, 11 ppm; Fe, <20ppm - Composition of test material, percentage of components: Ruthenium, 40.56%; Insolubles *n H₂O, <0.02% - Isomers composition: no data - Purity test date: 16-Jun-2015 - Lot/batch No.: 10715 - Expiration date of the lot/batch: 15-Jun-2016 - Stability under test conditions: no data - Storage condition of test material: recommended: dry storage; reported: 15-25 deg C, protected from light

Test material: **Ruthenium chloride / Ruthenium (III) chloride hydrate / 14898-67-0**

Form: **solid**

Composition type: Constituent	Reference substance: Ruthenium trichloride hydrate EC no.: 604-667-4 CAS no: 14898-67-0 IUPAC name: Ruthenium trichloride hydrate	Concentration range:
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Test material: **Ruthenium trichloride (hydrated solid)**

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

Composition type: Constituent	Reference substance: Ruthenium trichloride (hydrated solid) EC no.: CAS no: IUPAC name: Ruthenium trichloride (hydrated solid)	Concentration range:
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Test material: **Rhodium triiodide**

Form:

Composition type: Constituent	Reference substance: rhodium triiodide EC no.: 239-521-5 CAS no: 15492-38-3 IUPAC name: rhodium triiodide	Concentration range:
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Test material: **Ruthenium (III) Chloride hydrate**

Form: **solid**

Composition type: Constituent	Reference substance: Ruthenium (III) Chloride hydrate EC no.: CAS no: IUPAC name: Ruthenium (III) Chloride hydrate	Concentration range:
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Test material: **Ruthenium (III) chloride hydrate**

Form:

Composition type:	Reference substance: Ruthenium trichloride hydrate EC no.: 604-667-4 CAS no: 14898-67-0 IUPAC name: Ruthenium trichloride hydrate	Concentration range:
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3. Annex: Mode of action / Human relevance Framework

Section 5.6.3: Repeated dose toxicity

Detailed information on mode of action / Human relevance framework:

No data identified.

Section 5.7.3: Genetic toxicity

Detailed information on mode of action / Human relevance framework:

No data identified.

Section 5.9.3: Toxicity to reproduction

Detailed information on mode of action / Human relevance framework:

No data identified.