CHEMICAL SAFETY REPORT

Substance Name: tetracholorauric acid
EC Number: 240-948-4
CAS Number: 16903-35-8
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 Chapter 9 and 10 of part B of this CSR.
The above part A element applies to: joint CSR

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: joint CSR.

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: joint CSR.

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

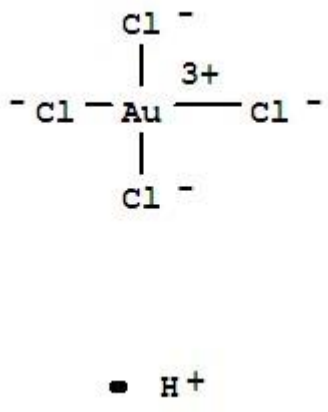
The substance tetracholorauric acid is a mono-constituent substance (inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).
The following public name is used:

Table 1.1. Substance identity

EC number:	240-948-4
EC name:	tetrachloroauric acid
CAS number (EC inventory):	16903-35-8
CAS number:	16903-35-8
IUPAC name:	Tetrachloroauric acid
Molecular formula:	AuCl4.H
Molecular weight range:	339.79

Structural formula:

Figure 1.1. TCA_structure.jpg



1.2. Composition of the substance

Overall information on composition

Composition	Related composition(s)
Tetrachloroauric acid - Boundary composition (boundary composition of the substance)	

Name: Tetrachloroauric acid - Boundary composition

State/form: solid: particulate/powder
Degree of purity: >=99 - <=100 % (w/w)
Description:

Table 1.2. Constituents (Tetrachloroauric acid - Boundary composition)

Constituent	Typical concentration	Concentration range	Remarks
Tetrachloroauric acid hydrate EC no.: 240-	>99 % (w/w)	>=99 - <=100 % (w/w)	

948-4			

Table 1.3. Impurities (Tetrachloroauric acid - Boundary composition)

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

1.3. Physicochemical properties

Table 1.4. Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state	Tetrachloroauric acid is an orange solid.	**Value used for CSA:** solid at 20°C and 101.3 kPa The statement on appearance is taken from the test material section of a GLP-compliant study on physico-chemical properties of the material and is considered suitable for use as the key study for this endpoint. Moreover, information on appearance is available from two peer reviewed handbooks (O'Neil 2006, Lide 2008). Although the methods used are not known the handbooks are considered reliable and suitable for use as supporting studies for this endpoint. Tetrachloroauric acid is also available as a water solution at concentration of 15 - 75 % (w/w).
Melting / freezing point	Melting of the test item, gold (III) chloride trihydrate, was observed at 75°C. Thermal decomposition starts immediately after melting at 75°C and continues in three steps up to 320°C with a total mass loss of 49.4 and 49.7 % in flowing artificial air and argon atmospheres, respectively.	**Value used for CSA:** 75°C at 101.3 kPa An experimental study to determine thermal decomposition of gold (III) chloride trihydrate was conducted using Simultaneous thermogravimetry - Differential thermal analysis (TG–DTA) coupled with TG/EGA–FTIR and EGA–MS techniques (Otto et al. 2014). The study was performed in a flowing artificial air and argon atmospheres in the temperature range of 30–600°C. The intermediate and final products of thermal decomposition were analysed by *ex situ* X-ray diffraction (XRD) and Fourier transformed infrared (FTIR)

		techniques. This is a non-GLP, non-guideline study but follows a well described method and is considered to be suitable for use as a key study for this endpoint.
Relative density	When solid, the relative density of tetrachloroauric acid is 3.9.	**Value used for CSA:** 3.9 at 20°C Information on density is available from two peer reviewed handbooks (O'Neil 2006, Lide 2008). Although the methods used are not known the handbooks are considered reliable and suitable for use as key studies for this endpoint. When solid, the relative density of tetrachloroauric acid is 3.9.
Granulometry	The test item was sieved over a 1000 µm sieve and 27.5 % (w/w) of the test item passed through the sieve. Due to the corrosiveness of the test item and due to the small fraction below 1000 µm the determination of the particle size distribution with laser diffraction was not possible. The portion with a particle size < 1000 µm was inspected optically under a microscope and the particle size was determined to be approximately ≥ 200 µm.	The particle size distribution of tetrachlorogold (III) acid hydrate was determined according to OECD guideline 110 (Winkler 2016). This study is reliable without restrictions as it is GLP-compliant and was conducted according to a standard guideline. The test item was sieved over a 1000 µm sieve and 27.5 % (w/w) of the test item passed through the sieve. Due to the corrosiveness of the test item and due to the small fraction below 1000 µm the determination of the particle size distribution with laser diffraction was not possible. The portion with a particle size < 1000 µm was inspected optically under a microscope and the particle size was determined to be approximately ≥ 200 µm.
Water solubility	Tetrachloroauric acid is very soluble in water. The water solubility of the test item at 20 °C is > 1076 g/L.	**Value used for CSA:** 1076g/L at 20°C The water solubility of the test item tetrachlorogold(III) acid hydrate at a temperature of 20 °C was determined according to the OECD 105 and A.6 guidelines (Winkler 2016). The preliminary visual experiments showed that the water solubility of the test item is > 10 mg/L, therefore the main test was conducted using the flask method. In the main test, no precipitate was observed in the flasks after the equilibration time. As the test item was dissolved completely no further analytical determination was performed. The water solubility was calculated from the initial weight. The water solubility of the test item at 20 °C was determined to be > 1076 g/L. This study is reliable without restrictions as it is GLP-compliant and was conducted according to standard guidelines,

		therefore is suitable for use as a key study for this endpoint. Information on water solubility is also available from two peer reviewed handbooks (O'Neil 2006, Lide 2008). Although the methods used are not known the handbooks are considered reliable and suitable for use as supporting studies for this endpoint. Both handbooks report the substance to be 'very soluble'.
Flammability	Standard enthalpy of the combustion reaction of tetrachloroauric acid was calculated to be +3726.2 kJ/mol. It was concluded that based on thermodynamical principles, the combustion reaction of tetrachloroauric acid is not possible.	**Value used for CSA:** not classified The flammability potential of tetrachloroauric acid was predicted based on the standard reaction enthalpy of the combustion reaction of tetrachloroauric acid (PMRC 2017). From the calculated standard enthalpy reaction, it was shown that the combustion of tetrachloroauric acid is a strong endothermic reaction (+3726.2 kJ/mol) and therefore the combustion reaction of tetrachloroauric acid is not possible. This information has been supplied in the form of a statement letter outlining the calculation approach. The standard reaction enthalpy of the combustion reaction of tetrachloroauric acid was calculated using a general standard reaction enthalpy equation and standard formation enthalpy of reagents and products taken from peer reviewed handbooks. It is considered reliable with restrictions and is suitable for use as key data.
Oxidising properties	Tetrachloroauric acid solution does not appear to have oxidising properties as no 'vigorous' burning was observed. This is considered relevant also for the solid form. Taking this into account the oxidising properties of the test item have been predicted negative.	**Value used for CSA:** non oxidising This information has been supplied in the form of a statement letter from the company (Johnson Matthey 2010). It is considered suitable for use as supporting data to waive this endpoint. Tetrachloroauric acid solution does not appear to have oxidising properties as no 'vigorous' burning was observed. This is considered relevant also for the solid form. The structure contains a halogen therefore testing would be required. However, there are no oxohalogen groups within the structure and a preliminary test undertaken by Johnson Matthey (2010) clearly shows that the test item does not possess oxidising properties. Taking the above into

		account the oxidising properties of the test item have been predicted negative.

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: other justification

Justification: see 'Remark' - Tetrachloroauric acid is an inorganic substance that forms a crystal lattice. Upon heating, it melts at 75°C and decomposition starts immediately after melting at 75°C (Otto et al. 2014). It is scientifically not plausible that tetrachloroauric acid could exist in molecular form in the gas phase due to its solid state structure. Thus, the concept of vapour pressure, i.e. the saturation pressure above a solid or liquid does not apply. Tetrachloroauric acid is soluble in water and if it dissolves, it dissolves into ions, which cannot evaporate. In consequence, the testing for vapour pressure is waived for tetrachloroauric acid, since such testing would not provide any meaningful information on the substance, nor information applicable to the assessment of environmental fate or for any further animal or environmental studies.

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

Reason: study technically not feasible

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

Information requirement: Surface tension

Reason: study scientifically not necessary / other information available

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

Information requirement: Flash point

Reason: study technically not feasible

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

Information requirement: Self-ignition temperature

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because the substance is a solid having a melting point <= 160°C [study scientifically not necessary / other information available]

Information requirement: Explosive properties

Reason: study scientifically not necessary / other information available

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

Information requirement: Oxidising properties

Reason: other justification

Justification: see 'Remark' - The structure contains a halogen therefore testing would be required. However, there are no oxohalogen groups within the structure and a preliminary test undertaken by Johnson Matthey clearly shows that the test item does not possess oxidising

properties. Taking this into account the oxidising properties of the test item have been predicted negative.

Discussion of physicochemical properties

Physico-chemical endpoints for tetrachloroauric acid have been completed based on GLP-compliant, guideline studies (Winkler 2016), published data (Otto et al. 2014), two peer-reviewed handbooks (Lide 2008, O'Neil 2006) or appropriate waivers.

Additional information:

Tetrachloroauric acid has been assigned a classification of Metal corrosivity 1 (H290) based on extreme low pH.

2. MANUFACTURE AND USES

2.1. Manufacture

Table 2.1. Manufacture

	Manufacture
M-1	**Manufacture of the substance (as such)** Further description of manufacturing process: Tetrachloroauric acid solution is made by hydrochloric acid dissolution of gold in the presence of chlorine gas. Alternative, the tetrachloroauric acid solution is made by dissolving gold in aqua regia (hydrochloric acid/nitric acid) with an excess of hydrochloric acid to decompose nitric acid. Afterwards the solution is adjusted to the appropriate concentration or evaporated to form solid Tetrachloroauric acid hydrate. Contributing activity/technique for the environment: **- Manufacture of the substance (as such)** Contributing activity/technique for the workers: **- Chemical reaction and further processing in closed process** **- Chemical reaction and further processing in closed continuous process** **- Chemical reaction and further processing in closed batch process** **- Evaporation** **- Liquid based granulation** **- Liquid-based granulation** **- Laboratory analyses of liquid substance** **- Laboratory analyses of solid substance** **- Handling of liquid substance at non-dedicated facilities** **- Handling of liquid substance** **- Small scale handling of liquid substance** **- Handling and transfer of solid substance** **- Wet cleaning** **- Vacuum cleaning** use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Related assessment: use assessed in a joint CSR

2.2. Identified uses

Table 2.2. Formulation

	Formulation
F-1	**Formulation** Further description of the use: Contributing activity/technique for the environment: **- Formulation** Contributing activity/technique for the workers: **- Handling and packaging of liquid substance** **- Small scale handling and packaging of liquid substance** **- Handling and transfer of solid substance** **- Formulation in open or semi-closed process of solid substance** **- Mixing or blending in batch process of liquid substance** **- Wet cleaning** **- Vacuum cleaning** **Product Category formulated:** PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents **Technical function of the substance:** no technical function use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year

	Substance supplied to that use: in a mixture Related assessment: use assessed in a joint CSR
F-2	**Formulation** Further description of the use: Contributing activity/technique for the environment: **- Formulation** Contributing activity/technique for the workers: **- Handling and packaging of liquid substance** **- Small scale handling and packaging of liquid substance** **- Formulation in fully contained process** **- Formulation in closed continuous process** **- Formulation in closed batch process** **- Formulation in open or semi-closed process** **- Mixing or blending in batch process** **- Wet cleaning** **Product Category formulated:** PC 30: Photo-chemicals **Technical function of the substance:** photochemical use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Substance supplied to that use: as such; in a mixture Related assessment: use assessed in a joint CSR

Table 2.3. Uses at industrial sites

	Uses at industrial sites
IW-1	**Use as an intermediate** Further description of the use: Contributing activity/technique for the environment: **- Use as an intermediate** Contributing activity/technique for the workers: **- Handling of liquid substance at non-dedicated facilities** **- Handling of liquid substance** **- Small scale handling of liquid substance** **- Chemical reaction step in closed process** **- Chemical reaction step in closed continuous process** **- Chemical reaction step in closed batch process** **- Chemical reaction step in open or semi-closed process** **- Mixing or blending in batch process** **- Laboratory analyses** **- Production of metal powders in wet process** **- Wet cleaning** **Sector of end use:** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals; SU 14: Manufacture of basic metals, including alloys **Technical function of the substance:** intermediate (precursor) use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Substance supplied to that use: in a mixture Subsequent service life relevant for that use: no Related assessment: use assessed in a joint CSR
IW-2	**Production of imaging and printing articles** Further description of the use: Contributing activity/technique for the environment: **- Production of imaging and printing articles**

	Contributing activity/technique for the workers: **- Handling of the substance** **- Small scale handling of the substance** **- Fully contained process** **- Closed continuous process** **- Closed batch process** **- Mixing or blending in batch process** **- Wet cleaning** **Product Category used:** PC 30: Photo-chemicals **Sector of end use:** SU 7: Printing and reproduction of recorded media **Technical function of the substance:** photochemical use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Substance supplied to that use: in a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: Service life of treated articles in photography Related assessment: use assessed in a joint CSR
IW-3	**Production of printing plates** Further description of the use: Contributing activity/technique for the environment: **- Production of printing plates** Contributing activity/technique for the workers: **- Handling of the substance** **- Fully contained process** **- Closed continuous process** **- Closed batch process** **- Extrusion** **- Wet cleaning** **Product Category used:** PC 30: Photo-chemicals **Sector of end use:** SU 7: Printing and reproduction of recorded media **Technical function of the substance:** photochemical use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Substance supplied to that use: in a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: Service life of treated articles in photography Related assessment: use assessed in a joint CSR
IW-4	**Application of imaging and printing chemicals** Further description of the use: Contributing activity/technique for the environment: **- Application of imaging and printing chemicals** Contributing activity/technique for the workers: **- Handling of the substance** **- Mixing or blending in batch process** **- Dipping and pouring** **- Wet cleaning** **Product Category used:** PC 30: Photo-chemicals **Sector of end use:** SU 7: Printing and reproduction of recorded media **Technical function of the substance:** photochemical use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Substance supplied to that use: in a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: Service life of treated articles in photography

	Related assessment: use assessed in a joint CSR
IW-5	**Use in electrochemical and galvanic plating** Further description of the use: Contributing activity/technique for the environment: **- Use in electrochemical and galvanic plating** Contributing activity/technique for the workers: **- Small scale handling of the substance** **- Open or semi-closed process** **- Dipping and pouring** **- Wet cleaning** **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products **Sector of end use:** SU 14: Manufacture of basic metals, including alloys; SU 15: Manufacture of fabricated metal products, except machinery and equipment **Technical function of the substance:** plating agents and metal surface treating agents use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Substance supplied to that use: in a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: Service life of treated articles Related assessment: use assessed in a joint CSR

Table 2.4. Uses by professional workers

	Uses by professional workers
PW-1	**Use in photographic applications** Further description of the use: Contributing activity/technique for the environment: **- Use in photographic applications** Contributing activity/technique for the workers: **- Handling of preparations at non-dedicated facilities** **- Handling of preparations at dedicated facilities** **- Small scale handling of preparations** **- Open or semi-closed process** **- Mixing or blending in batch process** **- Application of the substance by rolling or brushing** **Product Category used:** PC 30: Photo-chemicals **Sector of end use:** SU 7: Printing and reproduction of recorded media **Technical function of the substance:** photochemical use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Subsequent service life relevant for that use: no Related assessment: use assessed in a joint CSR
PW-2	**Use in electrochemical and galvanic plating** Further description of the use: Contributing activity/technique for the environment: **- Use in electrochemical and galvanic plating** Contributing activity/technique for the workers: **- Handling of preparations at non-dedicated facilities** **- Small scale handling of preparations** **- Open or semi-closed process** **- Dipping and pouring** **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products

	Sector of end use: SU 14: Manufacture of basic metals, including alloys; SU 15: Manufacture of fabricated metal products, except machinery and equipment **Technical function of the substance:** plating agents and metal surface treating agents use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Subsequent service life relevant for that use: no Related assessment: use assessed in a joint CSR

Table 2.5. Article service life

	Article service life
SL-1	**Service life of treated articles in photography** Further description of the use: Treated articles do not contain tetrachloroauric acid but gold in metallic form. Article used by: workers Substance intended to be released from article: no **Article category related to subsequent service life (AC):** AC 7: Metal articles ; AC 13: Plastic articles Contributing activity/technique for the environment: **- Service life of treated articles in photography (ERC11a)** Contributing activity/technique for consumers: Contributing activity/technique for the workers: **- Service life of treated articles in photography (PROC 21)** **Technical function of the substance**: photochemical use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Related assessment: use assessed in a joint CSR
SL-2	**Service life of treated articles** Further description of the use: Treated articles do not contain tetrachloroauric acid but gold in metallic form. Article used by: consumers Substance intended to be released from article: no **Article category related to subsequent service life (AC):** Contributing activity/technique for the environment: **- Service life of treated articles (ERC11a)** Contributing activity/technique for consumers: **- Service life of treated articles (AC 7)** Contributing activity/technique for the workers: **Technical function of the substance:** Gold is plated on an article use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=0 tonnes/year Related assessment: use assessed in a joint CSR

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Substance: Tetrachloroauric acid
Implementation: EU
Related composition: Tetrachloroauric acid - Boundary composition; The substance is classified as follows:

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

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

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

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

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:	Acute Tox. 4	H302: Harmful if swallowed.	
Acute toxicity - dermal:			data lacking
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:	Skin Corr. 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:			conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:	Route of exposure: Oral - Following a positive result in an *in vitro* micronucleus assay in the absence of metabolic activation, an *in vivo* micronucleus assay was conducted which produced a negative result		conclusive but not sufficient for classification
Carcinogenicity:			data lacking
Specific target organ toxicity – single exposure:			conclusive but not sufficient for classification
Specific target organ toxicity – repeated	STOT Rep. Exp. 2 Affected organs: Kidney Route of exposure: Oral	H373: May cause damage to organs <or state all organs affected, if known> through	

exposure:	- Other routes of exposure have not been evaluated due to the corrosive nature of the test material	prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.	

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

Labelling
Signal word: Danger
Hazard pictogram:

Figure 3.1.

GHS05: corrosion

Figure 3.2.

GHS07: exclamation mark

Figure 3.3.

GHS09: environment

Figure 3.4.

GHS08: health hazard

Hazard statements:

H290: May be corrosive to metals.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H318: Causes serious eye damage.

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

H411: Toxic to aquatic life with long lasting effects.

Precautionary statements:

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

P102: Keep out of reach of children.

P103: Read label before use.

P234: Keep only in original packaging.

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

P264: Wash ... thoroughly after handling.

P270: Do no eat, drink or smoke when using this product.

P273: Avoid release to the environment.

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

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

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

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:
A GLP-compliant OECD 106 guideline test is available with tetrachloroauric acid (Klawonn2016). A limited partitioning study with three soils was performed to determine the Kd values. The approach was considered adequate for the information requirements. The Kd values of 16185.05, 1827.01 and 595.32 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h. The Koc values of 2415679.1, 92273.4 and 34411.7 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h. A hydrolysis study was not considered scientifically necessary and therefore it was waived as tetrachloroauric acid is not expected to undergo hydrolysis in the environment. The biodegradation study has been waived as the substance is an inorganic.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

No relevant information available.

Data waiving

Information requirement: Hydrolysis

Reason: study scientifically not necessary / other information available

Justification: see 'Remark' - In accordance with section 1 of REACH Annex XI, the hydrolysis study does not need to be conducted as this substance is not expected to undergo hydrolysis in the environment due to a lack of hydrolysable functional groups and therefore testing does not appear scientifically necessary.

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available.

4.1.1.2.2. Phototransformation in water

No relevant information available.

4.1.1.2.3. Phototransformation in soil

No relevant information available.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

No relevant information available.

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: study technically not feasible

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

4.1.2.1.2. Simulation tests (water and sediments)

No relevant information available.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

4.1.2.2. Biodegradation in soil

No relevant information available.

4.1.3. Summary and discussion of degradation

4.2. Environmental distribution

4.2.1. Adsorption/desorption

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

Table 4.1. Studies on adsorption/desorption

Method	Results	Remarks
adsorption / desorption: screening batch equilibrium method according to OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method) The standard test guideline (OECD 121, Koc estimation by HPLC) is not suitable for inorganic compounds as the method has not been validated for any inorganic compounds and none of the recommended reference substances are inorganic compounds. Therefore, a limited partitioning study with three soils following the OECD 106 Batch equilibrium method was performed to determine the Kd values. The approach was considered adequate for the information requirements.	Adsorption coefficient: Koc: 677717.7 at 20°C (Org. C (%): 0.67) (room temperature, sampling time 8 h) Kd: 4540.71 at 20°C (Org. C (%): 0.67) (room temperature, sampling time 8 h) Koc: 55855.1 at 20°C (Org. C (%): 1.98) (room temperature, sampling time 24 h) Kd: 1105.93 at 20°C (Org. C (%): 1.98) (room temperature, sampling time 24 h) Koc: 67870.3 at 20°C (Org. C (%): 1.73) (room temperature, sampling time 24 h) Kd: 1174.16 at 20°C (Org. C (%): 1.73) (room temperature, sampling time 24 h) Mass balance (in %) at end of adsorption phase: 99.3 after 8h (#1) 97.6 after 24h (#2) 97.6 after 24h (#3)	1 (reliable without restriction) key study experimental study **Test material** 16903-35-8 / 240-948-4; Hydrogen tetrachloroaurate (III), Form: solid **Reference** Klawonn T. 2016

Discussion

The following information is taken into account for any environmental exposure assessment:
The Kd values of 16185.05, 1827.01 and 595.32 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h. The Koc values of 2415679.1, 92273.4 and 34411.7 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h. An equivalent Koc value of 197215 was calculated from the three soils, and was then used to calculate partition coefficients for the substance to other environmental matrices in addition to soil (e.g. suspended sediment). The equivalent Koc value results in a Kd value of 3944.3 for standard soil with 2 % organic carbon.

Additional information:

A study was conducted to determine the adsorption – desorption of tetrachloroauric acid according to OECD 106. A limited partitioning study with three soils was performed to determine the Kd values (Klawonn 2016). The approach was considered adequate for the information requirements.
The equilibrium times for tetrachloroauric acid are visually reached for soil 2.3 after 8 h, for soil 2.4 and 6S after 24h.
At equilibrium, the Koc values of 677717.7, 55855.1 and 67870.3 were determined for Soil 2.3, 2.4 and 6S, respectively. The Kd values of 4540.71, 1105.93 and 1174.16 were determined for Soil 2.3, 2.4 and 6S, respectively.
The Kd values of 16185.05, 1827.01 and 595.32 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h. The Koc values of 2415679.1, 92273.4 and 34411.7 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h.
Organic carbon normalised partition coefficients (Koc) for the three tested soils showed a similar degree of variability to the calculated Kd values. In order to extrapolate the results of the soil partitioning study to other environmental media the average organic carbon normalised partition

coefficient (Koc) was calculated for the three soils, and this was used to calculate the partitioning in the various standard environmental matrices. The average value was calculated as the mean of the log transformed values, which was then back transformed to give the average Koc value. An equivalent Koc value of 197215 was calculated from the three soils, and was then used to calculate partition coefficients for the substance to other environmental matrices in addition to soil (e.g. suspended sediment). The equivalent Koc value results in a Kd value of 3944.3 for standard soil with 2 % organic carbon. Unitless partition coefficients (Kcomp-water) can then be calculated from the equivalent Koc value to define the partitioning of this substance in standard suspended sediment (10 % organic carbon). A value of 5917 is calculated for Ksoil-water, and a value of 4931 is calculated for Ksusp-water. These partition coefficients are used to calculate soil and sediment PNEC values by equilibrium partitioning.
The equivalent Koc value is calculated as:
Koc= Kd/ Foc
Koc values were calculated for each individual soil using the known organic carbon content of each sample, and the mean value calculated from log Koc values.
Kd values for standard environmental media are then calculated from the equivalent Koc value as:
Kd = Foc x Koc
using fixed Foc values for the relevant environmental compartments (2 % for soil and 10 % for suspended sediment). This results in Kd values of 3944 for soil and 19721 for suspended sediment. The calculated Kd value for standard soil is slightly higher than the values determined in any of the experiments due to the higher content of organic carbon in the standard soil compared to the test soils.

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:
Adsorption – Desorption of tetrachloroauric acid was tested according to OECD 106 (Klawonn 2016). The Kd values of 16185.05, 1827.01 and 595.32 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h. The Koc values of 2415679.1, 92273.4 and 34411.7 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h.

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

No relevant information available.

4.3.2. Terrestrial bioaccumulation

No relevant information available.

4.3.3. Summary and discussion of bioaccumulation

4.4. Secondary poisoning

Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant (see CSR chapter 7.5 “PNEC derivation and other hazard conclusions)”).

5. HUMAN HEALTH HAZARD ASSESSMENT

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

5.1.1. Non-human information

The results of studies on absorption, metabolism, distribution and elimination are summarised in the following table:

Table 5.1. Studies on absorption, metabolism, distribution and elimination

Method	Results	Remarks
basic toxicokinetics *in vivo* rat (HsdHan:WIST) male/female oral: gavage Exposure regime: Doses/conc.: 80 mg/kg bw/day (nominal); Actual dose received was adjusted for density to 168 mg/kg/day 100 mg/kg bw/day (nominal); Actual dose received was adjusted for density to 210 mg/kg/day Blood samples were taken into an appropriate anticoagulant from rats at termination of the MTD study and the plasma was separated by centrifugation and stored frozen until analysis. In addition, overnight urine samples were collected from the same animals and stored frozen until analysis. All sample analysis was undertaken using inductively coupled plasma–mass spectrometry (ICP–MS). (Nexion 300D PerkinElmer, Waltham, MA). Samples were analysed in the standard mode. To 500 µl of the sample (urine and whole blood) was added 100 µl HCl 37% and 400 µl HNO3 70 %. Samples were then incubated during one hour at 80 °C. After incubation samples were further diluted with HNO3 0.7% (20-fold dilution). Rhodium was used as internal standard.	Main ADME results: absorption: Significant increases in gold content over the controls were measured in both the plasma and urine of rats treated with either 80 (actual dose: 168) or 100 (actual dose: 210) mg/kg/day tetrachloroauric acid	2 (reliable with restrictions) key study experimental study (justification available in appendix 2) **Reference** Vincent Dunon 2016
Justification for type of information: The process for gold analysis was undertaken on plasma and urine samples taken from rats on the oral Maximum Tolerated Dose (MTD) study with the test substance.		

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:

Dose Group	Dose level (mg/kg/day)	Matrix	Gender	Au (µg/l)
2	0	Plasma	Male	0.124
3	80(168)	Plasma	Male	7941
4	100(210)	Plasma	Male	4473
2	0	Plasma	Female	0.074
3	80(168)	Plasma	Female	5911
4	100(210)	Plasma	Female	6753
2	0	Urine	Male	1.688
3	80(168)	Urine	Male	13380
4	100(210)	Urine	Male	21599
2	0	Urine	Female	1.204
3	80(168)	Urine	Female	16932
4	100(210)	Urine	Female	5698

Value used for CSA:
Bioaccumulation potential: low bioaccumulation potential
Absorption rate - oral (%): 100
Absorption rate - dermal (%): 100
Absorption rate - inhalation (%): 100
Additional information:
The levels of gold in rat plasma and urine following oral tetrachloroauric acid treatment showed significant increases over the vehicle control rats demonstrating significant absorption of gold via this route of administration. However, there was no clear dose-related increase in the gold levels suggesting that a Cmax had been achieved in these rats at these dose levels. Also, in general, the excreted gold concertation detected in the urine samples were sufficiently high to suggest that there was a low bioaccumulation potential of gold in rats following oral dosing with tetrachloroauric acid.

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 5.2. 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: >464 mg/kg bw (male/female) based on: (test mat.)	2 (reliable with restrictions) key study experimental study **Test material** 16903-35-8 / 240-948-4, **Reference** Berthold K 1993

Data waiving

Information requirement: Acute toxicity after oral administration

Reason: study scientifically not necessary / other information available

Justification: In accordance with column 2 of REACH Annex VIII studies do not need to be conducted if the substance is classified as corrosive to the skin.

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

5.2.1.3. Acute toxicity: dermal

No relevant information available.

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VIII *in vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided

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 accordance with column 2 of REACH Annex VII and Annex VIII, acute toxicity studies do not need to be conducted since the substance is classified as corrosive to the skin. An existing non-GLP acute oral toxicity study (OECD Guideline 401) in rats suggested that the LD50 for tetrachloroauric(III) acid to be > 464 mg/kg bw. However, this was based on a study using test solutions of very low pH and not neutralised as in other subsequent studies

Value used for CSA:
Acute oral toxicity: adverse effect observed (LD50) 464mg/kg bw
Acute dermal toxicity: no study available
Acute inhalation toxicity: no study available

Additional information:
In accordance with column 2 of REACH Annex VII and Annex VIII, acute toxicity studies do not need to be conducted since the substance is classified as corrosive to the skin. A GLP acute oral toxicity study in rats was conducted in 1993 in accordance with OECD Guideline 401 (subsequently deleted in 2002) which suggested that the LD50 for tetrachloroauric(III) acid was > 464 mg/kg bw. The toxicity demonstrated in this study was considered to be related to the strong acidity of the test solutions since the formulation was not neutralised as in subsequent oral studies. The study is considered sufficient to meet the criteria for classification as acute toxicity under EC Regulation 1272/2008.

Justification for classification or non-classification:
An existing non-GLP acute oral toxicity study (OECD Guideline 401) in rats suggested that the LD50 for tetrachloroauric(III) acid to be > 464 mg/kg bw. The study result meets the criteria for classification as acute toxicity under EC Regulation 1272/2008 (Acute Tox. Category 4 H302: Harmful if swallowed).

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

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

Table 5.3. Studies on skin irritation

Method	Results	Remarks
rabbit [common species] (White	Other: corrosive - Criteria used for	1 (reliable without

Russian (Albino)) Coverage: occlusive (shaved) Vehicle: unchanged (no vehicle) according to OECD Guideline 404 (Acute Dermal Irritation / Corrosion) ; according to EU Method B.4 (Acute Toxicity: Dermal Irritation / Corrosion)	interpretation of results: not specified Yellow and black discoloration of the skin, depression and slight oedema - Severe diffuse coagulation necrosis of the skin at the application site and subcutis and cutaneous muscle. Severe focal deposition of black granular particles at these sites and at reticulin fibres and skeletal muscle was also found. (Time point: Immediately on patch removal after 4 hours) Reversibility: not specified (Any indication of irritation was marked by severe signs of corrosion to the skin - Due to the severity of the reaction, only one animal was exposed and assessed.)	restriction) key study experimental study **Test material** 16903-35-8 / 240-948-4 **Reference** Berthold K 1993

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

5.3.1.2. Human information

No relevant information available.

5.3.2. Eye

5.3.2.1. Non-human information

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]

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:
There was evidence of corrosivity when tetrachloroauric(III) acid was applied to the skin of one rabbit using a 4-hour occluded patch. The study was performed in accordance with OECD test guideline with GLP. Eye irritation test was waived since the available information indicates that the criteria are met for classification as corrosive to the skin. No data were identified relating to irritation to the respiratory tract. Given the result from the skin irritation study, tetrachloroauric acid is likely to cause respiratory irritation under physiological conditions.

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

Respiratory irritation: no study available

Additional information:
No data were identified in humans relating to skin or eye irritation, and no human or animal data in relation to respiratory irritation were found.

The 1993 GLP *in vivo* study for skin irritation showed that tetrachloroauric acid is corrosive to the skin. When applied to the shaved skin of one rabbit using a 4 -hour occluded patch the test substance caused corrosivity as defined by the clinical assessment of the skin injury. However, this result does not allow for accurate subcategory classification for skin corrosivity, hence, an in vitro skin corrosion assessment study was conducted (2013). In this study, the detection of skin tissue destruction after exposure times >3minutes and =/<1 hour defines the skin corrosion effect as Subcategory 1B. These skin corrosion studies indicate that the test substance would be irritant to eyes. The key and supporting skin irritation/corrosion studies are considered sufficient to meet the criteria for classification as skin corrosive and eye irritant under EC Regulation 1272/2008.

No data were identified relating to irritation to the respiratory tract. Given the result from the skin irritation study, tetrachloroauric acid is likely to cause respiratory irritation.

Effects on skin irritation/corrosion: corrosive

Justification for classification or non-classification:
Acceptable *in vivo* and *in vitro* skin irritation tests gave results that meet the criteria for classification for skin corrosivity and eye irritation under EC Regulation 1272/2008 (Skin Corr. 1B H314: Causes severe skin burns). The eye irritation studies were waived on the basis of the skin corrosivity. Consequently, classification for eye irritation is based upon the perceived risk and is assigned Eye Damage 1 H318: Causes serious eye damage.

5.4. Corrosivity

5.4.1. Non-human information

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

Table 5.4. Studies on skin irritation related to corrosivity

Method	Results	Remarks
Tissue studied: skin irritation / corrosion, other - Although it was not the intention to demonstrate skin corrosion in this OECD404 study, the unexpected result fulfilled the endpoint criteria rabbit [common species] (White Russian (Albino)) Coverage: occlusive (shaved) Vehicle: unchanged (no vehicle) according to OECD Guideline 404 (Acute Dermal Irritation / Corrosion) ; according to EU Method B.4 (Acute Toxicity: Dermal Irritation / Corrosion)	Other: corrosive - Criteria used for interpretation of results: not specified Yellow and black discoloration of the skin, depression and slight oedema - Severe diffuse coagulation necrosis of the skin at the application site and subcutis and cutaneous muscle. Severe focal deposition of black granular particles at these sites and at reticulin fibres and skeletal muscle was also found. (Time point: Immediately on patch removal after 4 hours) Reversibility: not specified (Any indication of irritation was marked by severe signs of corrosion to the skin - Due to the severity of the reaction, only one animal was exposed and assessed.)	1 (reliable without restriction) key study experimental study **Test material** 16903-35-8 / 240-948-4 **Reference** Berthold K 1993
Tissue studied: skin corrosion: *in vitro / ex vivo* according to OECD Guideline 435 (*In*	Category 1B (corrosive) based on GHS criteria; Criteria used for interpretation of results: EU	1 (reliable without restriction) supporting study

Vitro Membrane Barrier Test Method for Skin Corrosion)	penetration time (in minutes) Value: >3.69 - <5.11 (Under the given test conditions, tetrachloroauric acid showed corrosive effects and is classified as “corrosive” category 1B (R34))	experimental study **Test material** 16903-35-8 / 240-948-4 Form: Liquid **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 technically not feasible

Justification: the study does not need to be conducted because the available information indicates that the substance should be classified for respiratory sensitisation or corrosivity [study scientifically not necessary / other information available]; it is not feasible to conduct an *in vivo* study with the test substance as a consequence of its corrosive nature and strong acidity - Standard *in vivo* skin sensitisation tests such as the LLNA cannot be justified with this substance. *In vitro* alternatives have been considered.

Information requirement: Skin Sensitisation

Reason: other justification

Justification: Studies do not need to be conducted as the substance is very hydroscopic and forms a strong acid. The substance is also classified as corrosive. - All three validated *in vitro* tests for this endpoint would normally be conducted as each test (DPRA, h-CLAT, KeratinoSens) examines a specific step in the Adverse Outcome Pathway of skin sensitisation. However, at least one of these tests is unsuitable for the evaluation of metal substances and also the methods may be unduly affected by the acidity of the test material.

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 study was performed since the endpoint was waived based upon the corrosive nature of the test material to the skin
Value used for CSA: no study available
The following information is taken into account for any hazard / risk assessment:

Respiratory sensitisation

Value used for CSA: no study available
Justification for classification or non-classification:
The test substance has been classified as corrosive to the skin (Skin Corr. 1B) and, therefore, *in vivo* skin sensitisation studies have been waived. In addition, the three *in vitro* studies for the evaluation of skin sensitisation cannot be completed due to unsuitability for the evaluation of metals or the strong acidity of the test substance. Consequently, classification for this endpoint was not possible due to the lack of appropriate data.

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of studies are summarised in the following table:

Table 5.5. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks
rat [common rodent species] (CD / Crl:CD(SD)) male/female short-term repeated dose toxicity: oral (oral: gavage) 0 mg/kg bw/day (nominal) 50 mg/kg bw/day (nominal) 15 0mg/kg bw/day (nominal) 450 mg/kg bw/day (nominal) Vehicle: water Exposure: - Adaptation: 13 days - Pre-treatment period: 14 test days (TD 1 to TD 14) - Start of treatment on test day 15 - Males: - 33 treatment days (sacrifice on TD 48) - Females with litter: - 50 to 57 treatment days (sacrifice between TD 65 and 72) (once daily) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	NOAEL: 50 mg/kg bw/day (nominal) (male/female) based on: (test mat.) clinical signs; mortality ; body weight and weight gain ; food consumption and compound intake ; water consumption and compound intake ; haematology ; clinical biochemistry ; behaviour (functional findings) ; organ weights and organ / body weight ratios ; gross pathology ; histopathology: non-neoplastic **Target system / organ toxicity** Lowest effective dose /concentration: urinary: kidney (lowest effective dose/conc.: 150 mg/kg bw/day (actual dose received) ; treatment-related ; dose-response: yes)	1 (reliable without restriction) key study experimental study **Test material** Tetrachloroauric acid Form: liquid **Reference** Leuschner J 2017
rat [common rodent species] (HsdHan: WIST) male/female short-term repeated dose toxicity: oral (oral: gavage) 150 mg/kg bw/day (nominal)	Maximum-Tolerated-Dose (MTD): 100 mg/kg bw/day (nominal) (male/female) based on: (test mat. - Adjusted for density to 210 mg/kg/day) clinical signs; body weight and weight gain; food consumption and compound intake ;	2 (reliable with restrictions) supporting study experimental study **Test material** tetrachloroauric

100 mg/kg bw/day (nominal) 0 mg/kg bw/day (nominal) 80 mg/kg bw/day (nominal) 100 mg/kg bw/day (nominal) Vehicle: water Exposure: MTD study: three days (Group 1, MTD), seven days (Group 5, MTD) Fixed-dose study: 15 days (once daily) no guideline followed The objective of the study was to determine the maximum tolerated dose (MTD) of the test article, tetrachloroauric acid, following daily oral (gavage) administration to the rat. The toxicity of repeated daily administration at this dose level for 15 days was then assessed using naïve animals.	organ weights and organ / body weight ratios ; gross pathology **Target system / organ toxicity** Lowest effective dose /concentration: urinary: kidney (lowest effective dose/conc.: 150 ; treatment-related ; dose-response: yes)	acid, Form: liquid **Reference** Rhodes J 2015
rat [common rodent species] (HsdHan:WIST) male/female short-term repeated dose toxicity: oral (oral: gavage) 0 mg/kg bw/day (nominal) 10 mg/kg bw/day (nominal) 30 mg/kg bw/day (nominal) 100 mg/kg bw/day (nominal) Vehicle: water Exposure: The animals were dosed once daily to the males for 2 weeks prior to pairing, during the pairing period and until the day before necropsy and daily to the females for 2 weeks prior to pairing, during the pairing period and until Day 4 post-partum, inclusive. The females were allowed to litter and rear their offspring to Day 4 post-partum. Dosing was deferred if the animal was in or near parturition. The males were treated for 8 weeks prior to necropsy. (once daily) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	NOAEL: 21 mg/kg bw/day (nominal) (male/female) based on: (test mat. - Dose level of 10 mg/kg/day adjusted for density) clinical signs ; body weight and weight gain ; food consumption and compound intake ; organ weights and organ / body weight ratios ; gross pathology ; histopathology: non-neoplastic	3 (not reliable) disregarded due to major methodological deficiencies experimental study **Test material** tetrachloroauric acid, Form: liquid **Reference** Rhodes J 2015

5.6.1.2. Repeated dose toxicity: inhalation

No relevant information available.

Data waiving

Information requirement: short-term toxicity study (28 days) (inhalation)

Reason: study scientifically not necessary / other information available

Justification: a short-term repeat-dose toxicity study could not be justified based on the corrosive nature of the test substance to skin and the strong acidity of the test substance.

5.6.1.3. Repeated dose toxicity: dermal

No relevant information available.

Data waiving

Information requirement: short-term toxicity study (28 days) (dermal)

Reason: study technically not feasible

Justification: In accordance with column 2 of REACH Annex VIII *in vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided

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:
An MTD study (Rhodes 2015) was conducted to determine the maximum tolerated dose over short repeat-dose periods. The study was performed using dose levels unadjusted for the density of the test material, the adjustment being applied to the dose levels after completion of the study. The follow-up main study (Rhodes 2015), according to OECD422 guidelines was also conducted with dose levels unadjusted for the compound density. Formulation analysis of solutions prepared for the main OECD422 study gave results that were outside the acceptable range of variation of such analyses. Consequently, the main OECD422 study was repeated (LPT 2017) in which dose levels were prepared on a w/v basis thus taking into consideration the density of the test material in the production of the dose concentrations.
Value used for CSA (via oral route - systemic effects):
adverse effect observed
(NOAEL): (50 mg/kg bw/day) (subchronic); (rat [common rodent species])
Target organs: kidney
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
Justification for classification or non-classification:
The oral repeated-dose toxicity NOAEL was determined to be 50 mg/kg/day (over 33-days in male rats and up to 57 days in females with a litter) in the key repeat-dose toxicity study, and the lowest determined effect level was 150 mg/kg/day based on histopathological changes seen in the kidneys of the majority of animals at this dose level. The guidance dose ranges for Specific Target Organ Toxicity by repeat oral exposure (STOT-R) would be Category 1, <10-30 mg/kg/day, or Category 2, 10/30 – 100/300 mg/kg/day, depending on the duration of exposure (90-28 days respectively). Considering the lowest effect level of 150 mg/kg/day in the source study was associated with a slight degenerative effect on the rat kidney after 33-57 days of exposure, it is clear that this dose level falls outside the Category 1 criteria (i.e. the effective dose level exceeds the highest threshold >30 mg/kg/day). However, for Category 2 classification, the minimal effect level of 150 mg/kg/day exceeds the 90-day threshold of 100 mg/kg/day but is within the 28-day range of 30-300 mg/kg/day. Since the renal toxicity observed at the dose level of 150 mg/kg/day falls within the guideline criteria considered indicative of relevant toxic effects, Category 2 classification for STOT-RE classification is considered to be applicable.

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. *In vitro* data

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

Table 5.6. The results of *in vitro* genotoxicity studies are summarised in the following table:

Method	Results	Remarks
bacterial reverse mutation assay (*in vitro* gene mutation study in bacteria - Type of genotoxicity: gene mutation) *S. typhimurium* TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria] (Met. act.: with and without) Test concentrations: Experiment 1 (with and without S9): 1.563 (without S9 only), 3.125, 6.250, 12.5, 25, 50, 100, 500 (with S9 only) µg/plate Experiment 2 (without S9): 1.40 (TA100 and TA1537 only), 2.33, 3.89, 6.48, 10.8, 18, 30, 50 (TA98, TA1535 and TA102 only) µg/plate Experiment 3 (with S9): 7.78, 12.96, 21.6, 36, 60, 100, 500 µg/plate. The test article concentrations stated do not correct for metal content but are expressed as Tetrachloroauric acid solution (as supplied). Positive control substance(s): 9-aminoacridine ; 2-nitrofluorene ; sodium azide ; benzo(a)pyrene ; mitomycin C ; 2-aminoanthracene according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [*in vitro* gene mutation study in bacteria] ; according to UKEMS Guideline (Gatehouse et al 1990) ; according to ICH-S2A (1995) and ICH-S2B (1997) Gatehouse DG, Wilcox P, Forster R, Rowland IR and Callander RD (1990) Bacterial mutation assays. In “Basic Mutagenicity Tests UKEMS Recommended Procedures”. Report of the UKEMS Sub-committee on Guidelines for Mutagenicity Testing. Part I Revised. Ed Kirkland DJ. Cambridge University Press, pp. 13-61 ICH-S2A (1995) “Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals” ICH-S2B (1997) “Standard Battery for Genotoxicity Tests for Pharmaceuticals”	Test results: negative for *S. typhimurium* TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria]; met. act.: with and without genotoxicity: negative vehicle controls valid: yes negative controls valid: not applicable positive controls valid: yes Remark: all strains/cell types tested	1 (reliable without restriction) key study experimental study **Test material** 16903-35-8 / 240-948-4, Form: Orange liquid **Reference** McGarry S 2012 a
in vitro mammalian cell micronucleus test (*in vitro* cytogenicity / micronucleus study - Type of	Test results: for primary culture, other: human peripheral blood lymphocytes	1 (reliable without restriction) key study

genotoxicity: other: chromosome damage – micronuclei) primary culture, other: human peripheral blood lymphocytes [primary culture] (Met. act.: with and without) Test concentrations: ANALYSED - Experiment 1 (3+21 without S9): 0 (purified water), 40.00, 80.00, 140.0 µg/mL (plus positive control MMC 0.80 µg/mL) - Experiment 1 (3+21 with S9): 0 (purified water), 40.00, 70.00, 95.00, 125.0 µg/mL (plus positive control CPA 12.50 µg/mL) - Experiment 1 (24+24 without S9): 0 (purified water), 30.00, 45.00, 60.00 µg/mL (plus positive control VIN 0.04 µg/mL) - Experiment 2 (3+21 without S9): 0 (purified water), 30.00, 40.00, 60.00, 120.0 µg/mL (plus positive control MMC 0.80 µg/mL) - Experiment 3 (3+21 without S9): 0 (purified water), 40.00, 80.00, 140.0, 200.0 µg/mL (plus positive control MMC 0.80 µg/mL) - Experiment 3 (24+24 without S9): 0 (purified water), 30.00, 40.00, 45.00, 60.00 µg/mL (plus positive control VIN 0.10 µg/mL) TESTED - Range finder (3+21 and 24+24, with and without S9): 0, 12.33, 20.55, 34.24, 47.07, 95.12, 458.5, 264.2, 440.4, 734.0, 1223, 2039, 3398 µg/mL - Experiment 1 (3+21 without S9): 0, 20.00, 40.00, 60.00, 80.00, 100.0, 120.0, 140.0, 160.0, 180.0, 200.0, 250.0, 300.0, 400.0 µg/mL - Experiment 1 (3+21 with S9): 0, 20.00, 40.00, 60.00, 70.00, 80.00, 90.00, 95.00, 100.0, 110.0, 125.0, 150.0, 200.0 µg/mL - Experiments 1 and 3 (24+24 without S9): 0, 5.000, 10.00, 20.00, 25.00, 30.00, 35.00, 40.00, 45.00, 50.00, 60.00, 80.00, 100.0 µg/mL - Experiments 2 and 3 (3+21 without S9): 0, 10.00, 20.00, 30.00, 40.00, 50.00, 60.00, 80.00, 100.0, 120.0, 140.0, 160.0, 200.0 µg/mL - Positive controls: Mitomycin C: 0.60, 0.80 µg/mL, Cyclophosphamide: 6.25, 12.50 µg/mL, Vinblastine: 0.04, 0.06, 0.08 (0.10, 0.12 experiment 3 only) µg/mL The test article concentrations stated do not correct for metal content but are expressed as Tetrachloroauric acid solution (as supplied). Positive control substance(s): cyclophosphamide ; mitomycin C ; Vinblastine	[primary culture]; met. act.: with cytotoxicity: no vehicle controls valid: yes positive controls valid: yes Remark: all strains/cell types tested Test results: for primary culture, other: human peripheral blood lymphocytes [primary culture]; met. act.: without cytotoxicity: yes vehicle controls valid: yes positive controls valid: yes Remark: all strains/cell types tested	experimental study **Test material** 16903-35-8 / 240-948-4 Form: Orange liquid **Reference** Watters G 2013

according to OECD 487 (*In vitro* mammalian cell micronucleus test) OECD (2010) Genetic toxicology: OECD guideline for the testing of chemicals. Guideline 487: *In vitro* mammalian cell micronucleus test The test methodology is also based on accepted scientific/regulatory principles described in current guidelines for clastogenicity test *in vitro*.		
bacterial reverse mutation assay (*in vitro* gene mutation study in bacteria - Type of genotoxicity: gene mutation) *S. typhimurium* TA 98 [bacteria] (Met. act.: with and without) *S. typhimurium* TA 102 [bacteria] (Met. act.: with and without) *S. typhimurium* TA 100 [bacteria] (Met. act.: with and without) Test concentrations: In strains TA98 and TA102 (with and without S9): 0, 5, 15.81, 50, 158.1, 500, 1581, 5000 µg/plate. In strain TA102 (with and without S9): 0, 3.125 (without S9 only), 6.25, 12.5, 25, 50, 100, 160, 500 (with S9 only) µg/plate; The test article concentrations stated do not correct for metal content but are expressed as Tetrachloroauric acid solution (as supplied). Positive control substance(s): 2-nitrofluorene ; sodium azide ; benzo(a)pyrene ; mitomycin C ; Aminoanthracene no guideline followed Preliminary screening study to detect the ability of tetrachloroauric acid to induce gene mutation in three strains of *Salmonella typhimurium*. Principally equivalent to OECD Guideline 471: Bacterial Reverse Mutation Test, though utilising less strains than this guideline recommends. The study was performed to the study protocol and one amendment with two exceptions. 1) Following strain TA100 Experiment 1 treatments in the absence of S 9, the vehicle control values fell below the current historical ranges such that the data were not considered to be characteristic for the strain. These data were considered invalid for mutation assessment and were not be reported. Therefore, strain TA100 treatments in the absence and presence of S 9 were	Test results: negative for *S. typhimurium*, other: TA98, TA102, TA100 [bacteria]; met. act.: with and without genotoxicity: negative vehicle controls valid: yes negative controls valid: not applicable positive controls valid: yes Remark: all strains/cell types tested	1 (reliable without restriction) supporting study experimental study **Test material** 16903-35-8 / 240-948-4, Form: Orange liquid **Reference** McGarry S 2012b

repeated using a revised concentration range and are presented as Experiment 1 TA100 data. 2) Following preparation of one of the highest test article formulations, some of the remaining test article was discarded following the filtering process in error. All other remaining test article formulations were retained as per protocol and this deviation is considered not to have impacted on the integrity of the study.		
Bacillus subtilis recombination assay (*in vitro* DNA damage and/or repair study - Type of genotoxicity: DNA damage and/or repair) bacteria, other: *Bacillus subtilis* H17 [bacteria] (Met. act.: not specified) bacteria, other: *Bacillus subtilis* M45 [bacteria] (Met. act.: not specified) Test concentrations: Between 0.005 and 0.5 M (no further information) equivalent or similar to Kada et al. (1972) [Mutation Res., 16, 165-174] Rec assay using two strains of *Bacillus subtillis.*	Test results: negative for bacteria, other: *B. subtilis* [bacteria]; met. act.: not specified genotoxicity: negative cytotoxicity: not determined vehicle controls valid: not applicable negative controls valid: not examined positive controls valid: not examined Remark: all strains/cell types tested	2 (reliable with restrictions) supporting study experimental study **Test material** 16903-35-8 / 240-948-4, **Reference** Kanematsu N, Hara M, Kada T 1980

5.7.1.2. *In vivo* data

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

Table 5.7. *In vivo* genotoxicity studies

Method	Results	Remarks
micronucleus assay (*in vivo* mammalian somatic cell study: cytogenicity / erythrocyte micronucleus - Type of genotoxicity: chromosome aberration) rat (Wistar [rat]) male oral: gavage Cyclophosphamide - Route of administration: Oral gavage, 10 mL/kg dose volume. - Doses / concentrations: Single administration of 20 mg/kg cyclophosphamide in 0.9 % saline at 24 hours. according to OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) [*in vivo* mammalian somatic cell study: cytogenicity / erythrocyte micronucleus]	Genotoxicity: negative - Tetrachloroauric acid did not induce micronuclei in the polychromatic erythrocytes of the bone marrow of male rats treated up to100 mg/kg/day under the experimental conditions employed. (male) toxicity: no effects - No clinical signs of toxicity were observed in any animal following treatments with vehicle, Tetrachloroauric acid (at 25, 50 or 100 mg/kg/day) or the positive control (CPA). vehicle controls valid: yes positive controls valid: yes	1 (reliable without restriction) key study experimental study **Test material** 16903-35-8 / 240-948-4, Form: gas under pressure: refrigerated liquefied gas **Reference** Whitwell J 2015

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*):
A reverse mutation test was conducted in five histidine requiring strains of *Salmonella typhimurium* (Ames Test; OECD471)) under Annex VII of REACH regulations. As a consequence of a negative result in the Ames test, the Annex VIII *in vitro* tests were undertaken. To examine the potential to cause chromosome damage, a study of the induction of micronuclei in cultured human peripheral lymphocytes (OECD487) was performed. A positive result was obtained in this study.

Value used for CSA (genetic toxicity *in vitro*):
Genetic toxicity: adverse effect observed (positive)

The following information is taken into account for any hazard / risk assessment (genetic toxicity *in vivo*):
Due to the positive result in the *in vitro* micronucleus assay (OECD487), under the REACH regulations at the time, an *in vivo* test was required to be carried out and this was done under the wording of Annex VIII. Consequently, a rat bone marrow micronucleus assay (OECD474) was conducted to examine the potential to induce micronuclei in the polychromatic erythrocytes of the bone marrow of treated rats.

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

Justification for classification or non-classification
In consideration of the predominantly negative test results in highly reliable genotoxicity assays, no genotoxicity needs to be expected from exposure to tetrachloroauric acid. In consequence, no classification is required.

Additional information:
Tetrachloroauric acid was tested for its ability to induce reverse mutations in a screening and definitive Ames assay (McGarry 2012a, McGarry 2012b) in five strains of *Salmonella typhimurium* (TA98, TA100, TA102, TA1535 and TA1537). Three experiments were carried out with 7 to 8 test concentrations. There was no mutation induced at concentrations up to toxic concentrations in the presence and absence of rat liver S9 metabolic activation. Cytotoxicity was observed in various strains at various concentrations with and without metabolic activation. The definitive test was a GLP, guideline study following OECD 471 and is suitable for use as a key study.
In an *in vitro* experiment for chromosomal damage, cultured human peripheral blood lymphocytes were exposed to 12 to 13 concentrations of tetrachloroauric acid with and without activation for 24+24 and 3+21 hours. Tetrachloroauric acid was found to induce micronuclei in the absence of rat liver S9 metabolic activation when tested up to the limit of solubility (50.00 mg/mL), however a negative result was observed in the presence of metabolic activation when tested up to cytotoxic concentrations (Watters 2013). This was a GLP, guideline study following OECD 487 and is suitable for use as a key study.
In an *in vivo* study on chromosome aberration, male Han Wistar rats were orally gavaged with nominal concentrations of 25, 50 and 100 mg/kg/day tetrachloroauric acid on two consecutive days (Whitwell 2015). No evidence of micronuclei induction was observed in the polychromatic erythrocytes of the bone marrow at doses up to 100 mg/kg/day. No clinical signs of toxicity or notable effects on bodyweight were observed. This was a GLP, guideline study following OECD 474 and is suitable for use as a key study. The high dose level of 100 mg/kg/day was subsequently found to be below the likely MTD which was more likely to be in the range 210 -300 mg/kg/day. However, analysis of plasma and urine from rats on the MTD study for gold content demonstrated significant exposure but not dose dependent at nominal dose levels of 80 or 100 mg/kg/day (density adjusted levels 168 and 210 mg/kg/day). Therefore, it was concluded that this *in vivo* chromosome aberration study was conducted at dose levels which provided significant exposure to the animals.
In a recombination assay with bacterium *Bacillus subtilis* strains H17 and M45, tetrachloroauric acid produced a negative result for evidence of DNA damage and repair at concentrations between 0.005M and 0.5M (Kanematsu et al. 1980). This study is used as supporting evidence as it was a non-GLP and non-guideline study with limitations in reporting, published in a peer-reviewed journal.

Overall, there is no consistent evidence of genotoxicity below the cytotoxic concentration for tetrachloroauric acid.

Justification for selection of genetic toxicity endpoint

By applying a weight-of-evidence approach, after consideration of the predominantly negative test results of highly reliable *in-vitro* and *in-vivo* genotoxicity assays, the overall conclusion is reached that no genotoxicity needs to be expected from exposure to tetrachloroauric acid.

Endpoint Conclusion: No adverse effect observed (negative)

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

No relevant information available.

5.8.1.2. Carcinogenicity: inhalation

No relevant information available.

5.8.1.3. Carcinogenicity: dermal

No relevant information available.

5.8.1.4. Carcinogenicity: other routes

No relevant information available.

5.8.2. Human information

No relevant information available.

5.8.3. Summary and discussion of carcinogenicity

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

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

Table 5.8. Studies on fertility

Method	Results	Remarks
rat (CD / Crl:CD(SD)) male/female screening for reproductive / developmental toxicity oral: gavage 0 mg/kg bw/day (nominal) vehicle control 50 mg/kg bw/day (nominal) low dose 150 mg/kg bw/day (nominal) intermediate dose 450 mg/kg bw/day (nominal) high dose; dose was reduced to 375 mg/kg bw/day on the 2nd day of dosing and then to 300 mg/kg bw/day on the 3rd day of dosing Vehicle: water Exposure: - Adaptation: 13 days - Pre-treatment period: 14 test days (TD 1	**First parental generation (P0)** NOAEL (PO) 300 mg/kg bw/day (nominal)) (female) based on: reproductive performance [reproductive toxicity] **Second parental generation (P1)** **F1 generation** NOAEL (PO): 150 mg/kg bw/day (nominal) (male/female) based on: mortality ; body weight and weight gain ; organ weights and organ / body weight ratios ; gross pathology ; histopathology: non-neoplastic **F2 generation** **Overall reproductive toxicity** no Lowest effective dose / concentration 300 mg/kg bw/day (actual dose received)	1 (reliable without restriction) key study experimental study **Test material** Tetrachloroauric acid Form: liquid **Reference** Leuschner J 2017

to TD 14) - Start of treatment on test day 15 - Males: - 33 treatment days (sacrifice on TD 48) - Females with litter: - 50 to 57 treatment days (sacrifice between TD 65 and 72) (once daily) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)		
rat (HsdHan:WIST) male/female screening for reproductive / developmental toxicity oral: gavage 0 mg/kg bw/day (nominal) control 10 mg/kg bw/day (nominal) low dose. 21.0 mg/kg/day adjusted for density. 30 mg/kg bw/day (nominal) intermediate dose. 63.0 mg/kg/day adjusted for density 100 mg/kg bw/day (nominal) high dose. 210 mg/kg/day adjusted for density Exposure: males: 8 weeks females: 2 weeks prior to pairing, during the pairing period and until Day 4 post-partum (once daily) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	**First parental generation (P0)** NOAEL (PO) 100 mg/kg bw/day (nominal)) (male/female) based on: clinical signs [general toxicity] ; body weight and weight gain [general toxicity] ; food consumption and compound intake [general toxicity] ; organ weights and organ / body weight ratios [general toxicity] ; gross pathology [general toxicity] ; histopathology: non-neoplastic [general toxicity] ; reproductive performance [reproductive toxicity] **Second parental generation (P1)** **F1 generation** NOAEL (PO): 10 mg/kg bw/day (nominal) (male/female) based on: viability ; clinical signs ; mortality ; body weight and weight gain ; gross pathology	3 (not reliable) disregarded due to major methodological deficiencies experimental study **Test material** tetrachloroauric acid, Form: liquid **Reference** Rhodes J 2015

5.9.1.2. Human information

No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

No relevant information available.

5.9.2.2. Human information

No relevant information available.

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

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

An OECD422 main study (Rhodes 2015) was conducted in accordance with dose levels determined from a Maximum Tolerated Dose (MTD) study, however, the dose levels used were not appropriately adjusted for the compound density at preparation of the dose solutions and were adjusted post-dosing. Formulation analysis of the solutions prepared for the main OECD422 study gave results that were outside the acceptable range of variation of such analyses. Consequently, because of the

uncertainty of the actual dose levels used in this study, the main OECD422 study was repeated (LPT 2017) in which dose levels were prepared on a w/v basis thus taking into consideration the density of the test material in the production of the dose concentrations. It was the latter study that has, therefore, provided the appropriate data for this endpoint.
Value used for CSA (route: oral): no adverse effect observed (NOAEL) 300 mg/kg bw/day (subchronic); (rat [common rodent species])
Value used for CSA (route: dermal): no study available
Value used for CSA (route: inhalation): no study available
Developmental toxicity
The following information is taken into account for any hazard / risk assessment:
A guideline OECD422 study by oral administration to P0 and assessment of F1 pups for approximately 3 weeks post-coitum.
Value used for CSA (route: oral): adverse effect observed (NOAEL) 150 mg/kg bw/day (subchronic); (rat [common rodent species])
Value used for CSA (route: dermal): no study available
Value used for CSA (route: inhalation): no study available
Additional information:
During the post natal development period a reduced pup body weight was noted for the male and female pups of the high dose group (300 mg test item/kg b.w./day on lactation day 13. No further adverse effects were noted on the post natal development of the pups with respect to survival index, the endocrine/sexual development (T4 levels, ano-genital distance, male nipples counting) and gross abnormalities.
Justification for classification or non-classification:
The NOAELs for fertility/reproduction and for post natal development are higher than that for general toxicity, therefore, the test item is not classified for reproductive effects.

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No relevant information available.

5.10.1.2. Immunotoxicity

No relevant information available.

5.10.1.3. Specific investigations: other studies

No relevant information available.

5.10.2. Human information

No relevant information available. No relevant information available. No relevant information available.

5.10.3. Summary and discussion of other effects

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

5.11.1. Overview of typical dose descriptors for all endpoints

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

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type
Acute toxicity	oral	adverse effect observed (LD50): 464 mg/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	adverse effect observed (NOAEL): 50 mg/kg bw/day (subchronic; rat [common rodent species]) Target system/organs: urinary, kidney
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*: adverse effect observed (positive) *In vivo*: no adverse effect observed (negative)
Reproductive toxicity: effects on fertility	oral	no adverse effect observed (NOAEL): 300 mg/kg bw/day (subchronic; 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	adverse effect observed (NOAEL): 150 mg/kg bw/day (subchronic; rat [common rodent species])
Reproductive toxicity: developmental toxicity	dermal	no study available
Reproductive toxicity: developmental toxicity	inhalation	no study available

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

Table 5.10. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.14 mg/m³	repeated dose toxicity (Oral)

Inhalation	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Inhalation	Local effects - Long-term	high hazard (no threshold derived)	
Inhalation	Local effects - Acute	high hazard (no threshold derived)	
Dermal	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.04 mg/kg bw/day	repeated dose toxicity (Oral)
Dermal	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Local effects - Long-term	high hazard (no threshold derived)	
Dermal	Local effects - Acute	high hazard (no threshold derived)	
Eyes	Local effects	high hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEC

The substance, TCA, is to be registered in pure solid form, whereas the key study for PoD selection was conducted using the liquid form which constituted 41.5% Gold and 30.2% Chloride. Consequently, it is necessary to express the selected PoD dose levels in terms of pure TCA in order to calculate DNELs for the registered solid material.
Gold MW = 196.97
TCA MW = 339.79
Therefore, the fraction of Gold in TCA = 196.97 ÷ 339.79 = 0.579681568
The percentage Gold in a 1 mg/mL dosing solution in the OECD TG422 study is:
41.5% or 0.415 mg/mL
Expressed in terms of TCA = 0.415 ÷ 0.579681568 = 0.7159 mg/mL
Therefore, the PoD dose level of 50 mg/kg/day expressed as pure TCA = 35.8 mg/kg/day.
The corrected inhalatory NOAEC = oral NOAEL*(1/sRVrat
8hr)*(ABSoral/ABSinh)*(sRVhuman/wRV)
Where; ABS is Absorption; sRV is standard Respiratory Volume; wRV is worker Respiratory Volume
Therefore: NOAEC = (35.8 mg/kg/day)*(1/0.38 m3/kg)*(50/100)*(6.7m3/10m3) = 31.6 mg/m3

Overall Assessment Factor: 225

AF for dose response relationship: 1 (As the starting point for the DNEL is assumed to be a NOAEL this default factor is applied.)

AF for difference in duration of exposure: 6 (Assumes long-term worker handling is to be expected, but in any case, short-term human exposure is normally assessed using long-term DNELs. In this case the extrapolation is from a subacute animal study to chronic human exposure.)

AF for interspecies differences (allometric scaling): 1 (Scaling taken into consideration in the dose modification to inhalation exposure)

AF for other interspecies differences: 2.5 (In the absence of substance-specific toxicodynamic data to demonstrate interspecies differences the default factor of 2.5 is applied for systemic effects.)

AF for intraspecies differences: 5 (As a standard procedure for threshold effects the default factor of 5 is applied for Worker populations based on the fact that this sub population does not cover the very young, the very old and the very ill.)

AF for the quality of the whole database: 3 (Data from routes of exposure other than oral (e.g. dermal) are not available due to the corrosivity of the test material. For repeat-dose oral studies the formulation also required neutralisation of pH.)

Further explanation on hazard conclusions:

The relevance of this DNEL is based on the substance existing in solid form and consequently presenting a potential inhalation hazard from exposure to dust or particulates. In this event, the corrosive nature of the substance (as determined for the liquid formulation) would have serious effects on lung function and physiology. Therefore, a main focus in the workplace would be the avoidance of exposure to dusts and particulates of this substance.
This DNEL is “worst-case”, based on the assumption that 100% of the respired substance is absorbed. This is a reasonable assumption when considering the corrosive nature of the substance due to low pH of the hydrated form. The hygroscopic nature of the substance precludes the potential for dustiness assessment. Therefore, it is considered unlikely that *in silico* modelling using Multiple-Path Particle Dosimetry software could be conducted and, consequently, the proposed corrected inhalatory NOAEC remains unaltered at 31.6 mg/m3.

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

The conduct of an acute inhalation study was waived on the basis that TCA has been classified as skin corrosive (Category 1B). Therefore, in accordance with Column 2, REACH Annex VII, an acute toxicity inhalation study does not need to be conducted. In addition, the solid form of TCA is significantly hygroscopic and, therefore, dustiness assessment is considered impractical. Whilst it is considered most likely that the material would not be inhalable, the systemic long-term DNEL together with CLP skin and eye classifications are considered protective of this systemic acute/short-term exposure.

Inhalation Local effects - Long-term

Further explanation on hazard conclusions:

There are no data available by this route, but the substance is classified as skin corrosive (Category 1B) and would cause eye damage (Category 1). The most sensitive systemic long-term DNEL together with risk management measures associated with the CLP skin and eye classifications are considered for these exposure conditions are considered protective of this local long-term exposure.

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

There are no data available by this route, but the substance is classified as skin corrosive (Category 1B) and would cause eye damage (Category 1). The most sensitive systemic long-term DNEL together with the risk management measures associated with the CLP skin and eye classifications for these exposure conditions are considered protective of this local acute/short-term exposure.

Dermal Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEL

The substance, TCA, is to be registered in pure solid form, whereas the key study for PoD selection was conducted using the liquid form which constituted 41.5% Gold and 30.2% Chloride. Consequently, it is necessary to express the selected PoD dose levels in terms of pure TCA in order to calculate DNELs for the registered solid material.
Gold MW = 196.97
TCA MW = 339.79

Therefore, the fraction of Gold in TCA = 196.97 ÷ 339.79 = 0.579681568
The percentage Gold in a 1 mg/mL dosing solution in the OECD TG422 study is:
41.5% or 0.415 mg/mL
Expressed in terms of TCA = 0.415 ÷ 0.579681568 = 0.7159 mg/mL
Therefore, the PoD dose level of 50 mg/kg/day expressed as pure TCA = 35.8 mg/kg/day.
DNEL = oral NOAEL(modified)*1/Total Adjustment Factor OR 35.8*1/900 = 0.04 mg/kg/day

Overall Assessment Factor: 900

AF for dose response relationship: 1 (As the starting point for the DNEL is assumed to be a NOAEL this default factor is applied)

AF for difference in duration of exposure: 6 (Assumes long-term worker handling is to be expected, but in any case, short-term human exposure is normally assessed using long-term DNELs. In this case the extrapolation is from a subacute animal study to chronic human exposure)

AF for interspecies differences (allometric scaling): 4 (Required for scaling from oral administration. Extrapolates doses according to an assumption that equitoxic doses (when expressed in mg/kg bw/day) scale with body weight to the power 0.75)

AF for other interspecies differences: 2.5 (In the absence of substance-specific toxicodynamic data to demonstrate interspecies differences the default factor of 2.5 is applied for systemic effects)

AF for intraspecies differences: 5 (As a standard procedure for threshold effects the default factor of 5 is applied for Worker populations based on the fact that this sub population does not cover the very young, the very old and the very ill.)

AF for the quality of the whole database: 3 (Data from routes of exposure other than oral (e.g. dermal) are not available due to the corrosivity of the test material. For repeat-dose oral studies the formulation also required neutralisation of pH).

Further explanation on hazard conclusions:

This dermal DNEL based on systemic toxicity of the neutralised formulation of TCA and adjusted for pure TCA is relevant for the safe handling of pure TCA. Risk Management Measures will be quoted in the MSDS based on the corrosive nature of the substance and involve avoidance of skin and eye contact. In the event of accidental skin contact with pure TCA and the irreversible skin damage is dealt with, there is then the issue of potential subsequent systemic toxicity following any absorption, likely to be enhanced via damaged skin. In such a scenario this “worst case” assumption of 100% absorption of the substance in contact with the skin is considered to be the most appropriate.

Dermal Systemic effects - Acute

Further explanation on hazard conclusions:

The conduct of an acute dermal study was waived on the basis that TCA has been classified as skin corrosive (Category 1B). Since there is no established consensus methodology for the establishment of an acute toxicity DNEL and there are no specific data to demonstrate the potential for peak exposures via this route, the most sensitive systemic long-term DNEL together with the risk management measures associated with the CLP skin and eye classifications for these exposure conditions are considered protective of this systemic-acute/short-term exposure.

Dermal Local effects - Long-term

Further explanation on hazard conclusions:

Although there is no data available for this endpoint, the substance is assigned Category 1B for acute *in vitro* skin corrosion data and would cause eye damage (Category 1). The most sensitive systemic long-term DNEL together with the risk management measures associated with the CLP skin and eye classifications for these exposure conditions are considered protective of this local long-term exposure.

Dermal Local effects - Acute

Further explanation on hazard conclusions:

Although there is no data available for this endpoint, the substance is assigned Category 1B for acute *in vitro* skin corrosion data and would cause eye damage (Category 1). The most sensitive systemic long-term DNEL together with the risk management measures associated with the CLP skin and eye classifications for these exposure conditions are considered protective of this local

acute short-term exposure.

Discussion:

The DNELs have been derived for a threshold endpoint since it has been demonstrated in the key OECD TG422 study that data shows a dose-related effect with the neutralised liquid form of TCA. Default assessment factors have been used to derive the DNELs. Under certain circumstances it is possible to modify these based on knowledge of exposure conditions, human vs animal sensitivity, etc.

The TCA solution is corrosive due to low pH, therefore, DNELs cannot be set for skin and eye irritancy endpoints from the data available. This is confirmed by the classification of skin corrosivity (Category 1B) and of eye damage (Category 1 based on a pH of 1 for the solution). In addition, oral acute toxicity testing of non-neutralised TCA indicates a classification of acute category 4 although this classification is significantly affected by the acidity of the solution which caused some severe clinical effects precluding an accurate assessment of the acute response.

Since the substance, TCA, is to be registered as a pure solid, an extrapolation of the DNELs calculated for the neutralised material to account for the difference in purity was considered appropriate. Therefore, the Worker inhalation and dermal DNELs have been calculated from the PoD from the key oral OECD TG422 study, adjusted to reflect the pure TCA content. Under the calculation criteria, it is considered that the systemic chronic DNEL can be protective of the acute exposure scenario for pure TCA and is relevant for the inhalation and dermal hazards beyond the initial corrosivity. The additional caveats relating to the pure solid form of TCA would be based on the physico-chemical aspects relating to bioavailability/absorption as well as, specifically for inhalation exposure, “dustiness” and “respiratory tract deposition modelling”. However, due to the hygroscopic nature of the solid form of TCA, it is unlikely that “Dustiness” or particle size dosimetry could be conducted.

The dermal exposure of workers to pure solid material will be covered by the application of adequate risk management measures because of the corrosivity properties determined for the liquid form.

Table 5.11. Hazard conclusions for the general population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.035 mg/m³	repeated dose toxicity (Oral)
Inhalation	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Inhalation	Local effects - Long-term	medium hazard (no threshold derived)	
Inhalation	Local effects - Acute	medium hazard (no threshold derived)	
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	high hazard (no threshold derived)	

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEL

Modified dose descriptor starting point: NOAEC

The substance, TCA, is to be registered in pure solid form, whereas the key study for PoD selection was conducted using the liquid form which constituted 41.5% Gold and 30.2% Chloride. Consequently, it is necessary to express the selected PoD dose levels in terms of pure TCA in order to calculate DNELs for the registered solid material.
Gold MW = 196.97
TCA MW = 339.79
Therefore, the fraction of Gold in TCA = 196.97 ÷ 339.79 = 0.579681568
The percentage Gold in a 1 mg/mL dosing solution in the OECD TG422 study is:
41.5% or 0.415 mg/mL
Expressed in terms of TCA = 0.415 ÷ 0.579681568 = 0.7159 mg/mL
Therefore, the PoD dose level of 50 mg/kg/day expressed as pure TCA = 35.8 mg/kg/day.
Scaling from rat to human and from oral to inhalation = 35.8 mg/kg/day*1/4 = 8.95 mg/kg/day NAEL human; 8.95*70 = 626.5 mg/person/day; 626.5*1/20m^3 per person = 31.325 mg/m^3 NAEC (24 h). As for Workers extrapolation was also applied from 50% bioavailability by the oral route to 100% bioavailability by the inhalation route, therefore, the adjusted NAEC human (24 h) is 31.325*50/100 = 15.66 mg/m^3.

Overall Assessment Factor: 600

AF for dose response relationship: 1 (As the starting point for the DNEL is assumed to be a NOAEL this default factor is applied)

AF for difference in duration of exposure: 6 (Assumes long-term worker handling is to be expected, but in any case, short-term human exposure is normally assessed using long-term DNELs. In this case the extrapolation is from a subacute animal study to chronic human exposure.)

AF for interspecies differences (allometric scaling): 1 (Already taken into account for the dose modification)

AF for other interspecies differences: 2.5 (In the absence of substance-specific toxicodynamic data to demonstrate interspecies differences the default factor of 2.5 is applied for systemic effects.)

AF for intraspecies differences: 10 (As a standard procedure for threshold effects the default factor of 10 is applied for the general population.)

AF for the quality of the whole database: 3 (Data from routes of exposure other than oral (e.g. dermal) are not available due to the corrosivity of the test material. For repeat-dose oral studies the formulation also required neutralisation of pH.)

Further explanation on hazard conclusions:

Since the substance, TCA, is to be registered as a pure solid, an extrapolation of the DNELs calculated for the neutralised material to account for the difference in purity was considered appropriate. Therefore, the General population inhalation DNEL has been calculated from the PoD from the key oral OECD TG422 study, adjusted to reflect the pure TCA content and possible emissions during the use of the agent. The additional caveats relating to the pure solid form of

TCA would be based on the physico-chemical aspects relating to bioavailability/absorption as well as, specifically for inhalation exposure, “dustiness” and “respiratory tract deposition modelling”. However, due to the hygroscopic nature of the solid form of TCA, it is unlikely that “Dustiness” or particle size dosimetry could be conducted.

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

The conduct of an acute inhalation study was waived on the basis that TCA has been classified as skin corrosive (Category 1B). Therefore, in accordance with Column 2, REACH Annex VII, an acute toxicity inhalation study does not need to be conducted. In addition, the solid form of TCA is significantly hygroscopic and, therefore, dustiness assessment is considered impractical. Whilst it is considered most likely that the material would not be inhalable, the systemic long-term DNEL together with risk management measures associated with the CLP skin and eye classifications for these exposure conditions are considered protective of this systemic acute/short-term exposure.

Inhalation Local effects - Long-term

Further explanation on hazard conclusions:

There are no data available by this route, but the substance is classified as skin corrosive (Category 1B) and would cause eye damage (Category 1). The systemic long-term DNEL together with risk management measures associated with the CLP skin and eye classifications for these exposure conditions are considered protective of this local long-term exposure.

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

There are no data available by this route, but the substance is classified as skin corrosive (Category 1B) and would cause eye damage (Category 1). The systemic long-term DNEL together with risk management measures associated with the CLP skin and eye classifications for these exposure conditions are considered protective of this local acute/short-term exposure.

Dermal Systemic effects - Long-term

Further explanation on hazard conclusions:

Whilst dermal exposure to articles plated with gold as a consequence of using the test substance in the plating process, the consumer would not actually be exposed to the test substance via this route.

Dermal Systemic effects - Acute

Further explanation on hazard conclusions:

Whilst dermal exposure to articles plated with gold as a consequence of using the test substance in the plating process, the consumer would not actually be exposed to the test substance via this route.

Dermal Local effects - Long-term

Further explanation on hazard conclusions:

Whilst dermal exposure to articles plated with gold as a consequence of using the test substance in the plating process, the consumer would not actually be exposed to the test substance via this route.

Dermal Local effects - Acute

Further explanation on hazard conclusions:

Whilst dermal exposure to articles plated with gold as a consequence of using the test substance in the plating process, the consumer would not actually be exposed to the test substance via this route.

Oral Systemic effects - Long-term

Further explanation on hazard conclusions:

Whilst dermal exposure to articles plated with gold as a consequence of using the test substance in the plating process, the consumer would not actually be exposed to the test substance via this route.

Oral Systemic effects - Acute

Further explanation on hazard conclusions:

Whilst dermal exposure to articles plated with gold as a consequence of using the test substance in the plating process, the consumer would not actually be exposed to the test substance via this route.

Discussion:

Since the test substance is to be registered as a pure solid, an extrapolation of the inhalatory DNEL calculated for the neutralised material to account for the difference in purity was considered appropriate. Therefore, the General population inhalation DNEL has been calculated from the PoD from the key oral OECD TG422 study, adjusted to reflect the pure test substance content. The additional caveats relating to the pure solid form of the test substance would be based on the physico-chemical aspects relating to bioavailability/absorption as well as, specifically for inhalation exposure, “dustiness” and “respiratory tract deposition modelling”. However, due to the hygroscopic nature of the solid form of the test substance, it is unlikely that “Dustiness” or particle size dosimetry could be conducted.

The oral route of exposure is not considered relevant for the general population. Also, for the general population, whilst dermal exposure to articles plated with gold as a consequence of using tetrachloroauric acid in the plating process, the consumer would not actually be exposed to the substance via this route. However, there was considered to be a requirement to assess potential exposure to the general public within a certain distance from stack emissions at manufacturing plants. Therefore, general population inhalation DNEL has been calculated.

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: Tetrachloroauric acid

Related composition: Tetrachloroauric acid - Boundary composition (solid: particulate/powder) ;

Classification: conclusive but not sufficient for classification

6.2. Flammability

Flammability

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

Table 6.1. Information on flammability

Method	Results	Remarks
flammable solids no guideline available To investigate the flammability potential of tetrachloroauric acid, the standard reaction enthalpy of the combustion reaction of tetrachloroauric acid was calculated.	Evaluation of results: not classified based on GHS criteria Study results: Flammable solids: Calculation of standard enthalpy of the combustion reaction (See 'Remark' - Standard enthalpy of the combustion reaction of tetrachloroauric acid is +3726.2 kJ/mol.) Remarks: From the calculated standard enthalpy reaction, it is shown that the combustion of tetrachloroauric acid is a strong endothermic reaction (+3726.2 kJ/mol). Based on thermodynamical principles, the combustion reaction of tetrachloroauric acid is not possible.	2 (reliable with restrictions) key study calculation (if not (Q)SAR) (justification available in appendix 2) **Test material** Tetrachloroauric acid, Form: liquid **Reference** Precious Metals and Rhenium Consortium 2017
Justification for type of information: A calculation approach has been used in order to determine the standard reaction enthalpy of the combustion reaction of TCA.		

Discussion

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

Flammability

Key value for chemical safety assessment: Flammability: not classified

Standard enthalpy of the combustion reaction of tetrachloroauric acid was calculated to be +3726.2 kJ/mol. It was concluded that based on thermodynamical principles, the combustion reaction of tetrachloroauric acid is not possible.

Additional information:

The flammability potential of tetrachloroauric acid was predicted based on the standard reaction enthalpy of the combustion reaction of tetrachloroauric acid (PMRC 2017).

From the calculated standard enthalpy reaction, it was shown that the combustion of tetrachloroauric acid is a strong endothermic reaction (+3726.2 kJ/mol) and therefore the combustion reaction of tetrachloroauric acid is not possible.

This information has been supplied in the form of a statement letter outlining the calculation approach. The standard reaction enthalpy of the combustion reaction of tetrachloroauric acid was calculated using a general standard reaction enthalpy equation and standard formation enthalpy of reagents and products taken from peer reviewed handbooks. It is considered reliable with restrictions and is suitable for use as key data.

Flash Point

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

Classification according to GHS

Name: Tetrachloroauric acid

Related composition: Tetrachloroauric acid - Boundary composition (solid: particulate/powder)

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

Justification for classification or non-classification:

Tetrachloroauric acid is not classified as a readily combustible solid under Division 4.1 as based on the calculated standard enthalpy of the combustion reaction of tetrachloroauric acid and thermodynamical principles, it can be predicted that the combustion reaction of tetrachloroauric acid is not possible.

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 equivalent or similar to EU Method A.17 (Oxidising Properties (Solids))	Evaluation of results: GHS criteria not met Test results: Oxidising solids: 5 g of cellulose mixed with 10 g of aqueous tetrachloroauric acid is acid solution: preliminary test: (no vigorous burning observed)	2 (reliable with restrictions) supporting study experimental study **Test material** 16903-35-8 / 240-948-4 **Reference** Johnson Matthey Technology Centre 2010

Data waiving: see CSR section 1.3 Physicochemical properties.

Discussion

The following information is taken into account for any hazard / risk assessment:
Tetrachloroauric acid solution does not appear to have oxidising properties as no ‘vigorous’ burning was observed. This is considered relevant also for the solid form. Taking this into account the oxidising properties of the test item have been predicted negative.

Value used for CSA:

Oxidising properties: non-oxidising

Additional information:

This information has been supplied in the form of a statement letter from the company (Johnson Matthey 2010). It is considered suitable for use as supporting data to waive this endpoint.
Tetrachloroauric acid solution does not appear to have oxidising properties as no ‘vigorous’ burning was observed. This is considered relevant also for the solid form.
The structure contains a halogen therefore testing would be required. However, there are no oxohalogen groups within the structure and a preliminary test undertaken by Johnson Matthey (2010) clearly shows that the test item does not possess oxidising properties. Taking the above into account

the oxidising properties of the test item have been predicted negative.

Classification according to GHS

Name: Tetrachloroauric acid

Related composition: Tetrachloroauric acid - Boundary composition (solid: particulate/powder);

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

Justification for classification or non-classification:

Tetrachloroauric acid is not classified for oxidising properties. The structure contains a halogen therefore testing would be required. However, there are no oxohalogen groups within the structure and a preliminary test undertaken by Johnson Matthey (2010) clearly shows that the test item does not possess oxidising properties. Taking the above into account the oxidising properties of the test item have been predicted negative.

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

Additional information:
Acute toxicity data are available for tetrachloroauric acid for fish, invertebrates, algae and microorganisms.

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
Arctic Grayling, Coho Salmon, Rainbow Trout freshwater short-term toxicity to fish equivalent or similar to ASTM (1988) Standard practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians. Report No. E-729-88. American Society for Testing and Materials, Philadelphia. 96-hour static toxicity tests on three species of fish at both alevin and juvenile life stages.	LC50 (96h): 16.8 mg/L element - gold (nominal) based on: mortality (Arctic greyling alevins. 95% CL: 14.3 - 19.7 mg/L. Corresponding to 29.1 mg/L tetrachloroauric acid) LC50 (96h): 14.4 mg/L element - gold (nominal) based on: mortality (Arctic greyling juvelines. 95% CL: 12.1 - 17.2 mg/L. Corresponding to 24.9 mg/L tetrachloroauric acid) LC50 (96h): 33.5 mg/L element - gold (nominal) based on: mortality (Coho salmon alevins. 95% CL: 27.7 - 60.6 mg/L. Corresponding to 58.0 mg/L tetrachloroauric acid) LC50 (96h): 14.1 mg/L element - gold (nominal) based on: mortality (Coho salmon juveniles. 95% CL: 11.8 - 16.7 mg/L. Corresponding to 24.4 mg/L tetrachloroauric acid) LC50 (96h): 9.1 mg/L element - gold (nominal) based on: mortality (Rainbow trout alevins. 95% CL: 7.0 - 11.8 mg/L. Corresponding to 15.7 mg/L tetrachloroauric acid) LC50 (96h): 10.7 mg/L element - gold (nominal) based on: mortality (Rainbow trout juveniles. 95% CL: 8.6 - 13.4 mg/L. Corresponding to 18.5 mg/L tetrachloroauric acid)	2 (reliable with restrictions) key study experimental study **Test material** 16903-35-8 / 240-948-4; HAuCl4.3H2O, **Reference** Buhl KJ, Hamilton SJ 1991
Danio rerio (previous name: *Brachydanio rerio*) freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test)	NOEC (96h): 2 mg/L test mat. (not specified) based on: mortality (No mortality at the threshold concentration.) NOEC (96h): 2 mg/L test mat. (not specified) based on: visible adverse effects (No visible adverse effects at the threshold concentration.)	2 (reliable with restrictions) supporting study experimental study **Test material** gold (III) chloride trihydrate, Form: not specified **Reference** García-Cambero

		JP; García MN; López GD; Herranz AL; Cuevas L; Pérez-Pastrana E; Cuadal JS; Castelltort MR; Calvo AC 2013
Danio rerio and *Oryzias latipes* freshwater short-term toxicity to fish according to OECD Guideline 212 (Fish, Short-term Toxicity Test on Embryo and Sac-fry Stages)	EC50 (168h): 3.98 mg/L test mat. - tetrachloroauric acid (nominal) based on: morphology - development (*D. rerio*; effect concentrations reported based on Au(III), converted to tetrachloroauric acid, based on molecular weight.) EC50 (16d): 7.78 mg/L test mat. - tetrachloroauric acid (nominal) based on: morphology - development (*O. latipes*; effect concentrations reported based on Au(III), converted to tetrachloroauric acid, based on molecular weight.)	3 (not reliable) disregarded due to major methodological deficiencies experimental study **Test material** gold (III) chloride, Form: solid: particulate/powder - **Reference** Nam SH, Lee WM, Shin YJ, Yoon SJ, Kim SW, Kwak JI and An YJ 2014

Discussion

The following information is taken into account for acute fish toxicity for the derivation of PNEC:
LC50 values were determined for three species of fish, at two life stages. The lowest 96-hour LC50 is 9.1 mg Au/L for rainbow trout alevins. This corresponds to a 96-hour LC50 value of 15.7 mg/L based on tetrachloroauric acid.

Value used for CSA:
LC50 for freshwater fish: 15.7 mg/L

Additional information:
Data are available from a published, near guideline 96-hour toxicity test on three species of fish at alevin and juvenile life stages (Buhl & Hamilton 1991). The test using tetrachloroauric acid was carried out with a geometric series of 6 -10 nominal gold concentrations. Results are reported as nominal gold concentrations. Despite the deviations from a guideline study, this study is considered acceptable as the key study for this endpoint.
Supporting data are available from published study conducted with *Danio rerio* according to the OECD 203 guideline (Garcia-Cambero 2013). Fish were exposed to gold (III) chloride trihydrate at single concentration of 2 mg/L for 96 hours. This study is considered suitable as a supporting study for this endpoint.
The acute toxicity of gold (III) chloride to embryos of *Danio rerio* and *Oryzias latipes* was tested in a study according to OECD 212 guideline (Nam et al. 2014). Embryos of *Danio rerio* and *Oryzias latipes* were exposed to a range of 10 or 5 nominal concentrations for 168 hours post-fertilisation and for 16 days post-fertilisation, respectively. This study is considered unreliable as the toxicity values have limitation due to wide gap between the two flanking concentrations of 0.1 and 5.2 mg/L for *D. rerio* and 4 and 5 mg/L for *O. latipes*.Therefore, the study has been disregarded.

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) Deviation from test guideline as EPA 'Moderately hard water' medium was used. This is due to chelating agents in the standard test media that are known to interact with the test substance.	EC50 (48h): 4.8 mg/L test mat. (meas. (not specified)) based on: mobility (Tetrachloroauric acid concentration calculated from measured gold concentration. 95% confidence interval: 2.5 - 9.3 mg/L) EC50 (48h): 5.5 mg/L test mat. (nominal) based on: mobility (95% confidence interval: 3.1 - 9.8 mg/L)	1 (reliable without restriction) key study experimental study **Test material** 16903-35-8 / 240-948-4, **Reference** Brixham Environmental Laboratory 2012 a
*Daphnia magna, Simocephalus mixtus and Moina macrocopa*freshwater static according to OECD Guideline 202 (*Daphnia* sp. Acute Immobilisation Test)	EC50 (48h): 1.04 mg/L test mat. - tetrachloroauric acid (nominal) based on: mobility (*Daphnia magna*; effect concentrations reported based on Au(III), converted to tetrachloroauric acid.) EC50 (48h): 1.04 mg/L test mat. - tetrachloroauric acid (nominal) based on: mobility (*Moina macrocopa*; effect concentrations reported based on Au(III), converted to tetrachloroauric acid.) EC50 (24h): 4.05 mg/L test mat. - tetrachloroauric acid (nominal) based on: mobility (*Simocephalus mixtus*; effect concentrations reported based on Au(III), converted to tetrachloroauric acid.)	2 (reliable with restrictions) supporting study experimental study **Test material** gold (III) chloride, Form: solid: particulate/powder - **Reference** Nam SH, Lee WM, Shin YJ, Yoon SJ, Kim SW, Kwak JI and An YJ 2014
Daphnia magna freshwater static according to OECD Guideline 202 (*Daphnia* sp. Acute Immobilisation Test)	EC50 (48h): 1.34 mg/L (estimated) (95% IC: 1.14–1.58 mg/L)	2 (reliable with restrictions) supporting study experimental study **Test material** gold (III) chloride trihydrate, Form: not specified **Reference** García-Cambero JP; García MN; López GD; Herranz AL; Cuevas L; Pérez-Pastrana E; Cuadal JS; Castelltort MR; Calvo AC 2013

Daphnia magna freshwater static according to OECD Guideline 202 (*Daphnia* sp. Acute Immobilisation Test)	LC50 (48h): ca.2 mg/L test mat. (nominal) based on: mortality	3 (not reliable) disregarded due to major methodological deficiencies experimental study **Test material** tetra chloroauric acid, Form: not specified **Reference** Li T, Albee B, Alemayehu M, Diaz R, Ingham L, Kamal S, Rodriguez M, Bishnoi SW 2010

Discussion

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:
The lowest 48-h EC50 for *Daphnia magna* was determined to be 1.04 mg tetrachloroauric acid/L.

Value used for CSA:
EC50/LC50 for freshwater invertebrates: 1.04 mg/L

Additional information:
Data are available from a GLP-compliant study following OECD Guideline 202, with a minor deviation in the test media used due to potential for the standard media to interfere with the test item. A range-finding test and definitive test were carried out using 6 test concentrations and a control. Four replicates were used and results were reported based on measured concentrations and as nominal tetrachloroauric acid concentrations (Brixham 2012a). This study is considered to be suitable for use as a key study for this endpoint. The 48-hour EC50 for tetrachloroauric acid was reported as 4.8 mg/L (measured concentration).
Data are available from a published guideline study for gold (III) chloride. Tests were conducted on three aquatic invertebrate species (*Daphnia magna*, *Moina macrocopa* and *Simocephalus mixtu*s) with 8 to 9 test concentrations for 48 hours. Each treatment consisted of 4 replicates with 5 test organisms per replicate and results were reported as nominal concentrations (Nam et al. 2014). Effect concentrations were converted to tetrachloroauric acid concentrations on the basis of molecular weight. The 48-h EC50 was determined to be 1.04 mg/L tetrachloroauric acid (0.6 mg Au(III)/L) based on mobility for *D. magna* and *M. macrocopa*, and the 24-h EC50 was 4.02 mg/L tetrachloroauric acid (2.35 mg Au(III)/L) based on mobility for *S. mixtus*. This study is considered to be suitable for use as a supporting study for this endpoint and was used to determine aquatic PNECs as the result is lower than the EC50 determined in the short-term study with *Daphnia magna* (Brixham 2012a).
The acute toxicity of gold (III) chloride trihydrate to invertebrates was also tested in a study according to the OECD 202 guideline (Garcia-Cambero 2013). Daphnids were exposed to the range of test item concentrations between 0.5 and 5 mg /L for 48 hours. This study is considered reliable with restrictions and is suitable to use as a supporting study for this endpoint. The 48-h EC50 was estimated to be 1.34 mg/L (1.14–1.58, 95% IC) for *Daphnia magna*.
Data on acute toxicity of tetra aurochloric acid are also available from a published study with *Daphnia magna* conducted according to OECD 202 guideline (Li et al. 2010), *Daphnia magna* was exposed to gold ions in form of tetraaurochloric acid in standard synthetic freshwater for 48 hours. Test included a set of three to five concentrations and the SSF control group but the test concentrations are not reported. The 48-hour LC50 for *Daphnia magna* was determined to be ~2 mg tetrachloroauric acid/L. Due to major deficiencies in the method description and in reporting results this study is considered not reliable.

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] Culture medium used was a modified ISO growth medium prepared as suggested in the difficult substances guidance document. The deviation from the guideline was required due to chelating agents found in the standard media that can interfere with the test substance.	EC50 (72h): 2.6 mg/L test mat. (meas. (arithm. mean)) based on: biomass - yield (Tetrachloroauric acid concentration calculated from measured gold concentration. 95% confidence intervals: 2.5 - 2.8 mg/L) EC50 (72h): 2.8 mg/L test mat. (nominal) based on: biomass - yield (95% confidence intervals: 2.7 - 3.0 mg/L) EC50 (72h): >9 mg/L test mat. (meas. (arithm. mean)) based on: growth rate (Tetrachloroauric acid concentration calculated from measured gold concentration.) EC50 (72h): >10 mg/L test mat. (nominal) based on: growth rate NOEC (72h): 0.9 mg/L test mat. (meas. (arithm. mean)) based on: biomass - yield (Tetrachloroauric acid concentration calculated from measured gold concentration.) NOEC (72h): 0.98 mg/L test mat. (nominal) based on: biomass - yield NOEC (72h): 0.9 mg/L test mat. (meas. (arithm. mean)) based on: growth rate (Tetrachloroauric acid concentration calculated from measured gold concentration.) NOEC (72h): 0.98 mg/L test mat. (nominal) based on: growth rate	1 (reliable without restriction) key study experimental study **Test material** 16903-35-8 / 240-948-4, **Reference** Brixham Environmental Laboratory 2012b
Pseudokirchneriella subcapitata (previous names*: Raphidocelis subcapitata, Selenastrum capricornutum*) and *Euglena gracilis* (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006] Study also performed according to Blaise and Vasseur 2005.	NOEC (72h): 1.73 mg/L test mat. - tetrachloroauric acid (nominal) based on: biomass (*P. subcapitata*; effect concentrations reported for Au(III), converted to tetrachloroauric acid, based on molecular weight.) EC10 (72h): 1.02 mg/L test mat. - tetrachloroauric acid (nominal) based on: biomass (*P. subcapitata*; effect concentrations reported for Au(III), converted to tetrachloroauric acid, based on molecular weight.) EC10 (72h): 0.002 mg/L test mat. - tetrachloroauric acid (nominal) based on: biomass (*E. gracilis*; effect concentrations reported for Au(III), converted to tetrachloroauric acid, based on molecular weight.)	2 (reliable with restrictions) supporting study experimental study **Test material** gold (III) chloride, Form: solid: particulate/powder **Reference** Nam SH, Lee WM, Shin YJ, Yoon SJ, Kim SW, Kwak JI and An YJ 2014

Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006]	EC50 (72h): 1.91 mg/L test mat. (not specified) based on: biomass (95% IC: 1.30–2.83)	2 (reliable with restrictions) supporting study experimental study **Test material** gold (III) chloride trihydrate, Form: not specified **Reference** García-Cambero JP; García MN; López GD; Herranz AL; Cuevas L; Pérez-Pastrana E; Cuadal JS; Castelltort MR; Calvo AC 2013

Discussion

Effects on algae / cyanobacteria

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:
The EC50 for tetrachloroauric acid is reported to be >9.0 mg/L (measured concentration) based on growth rate.
The NOEC for tetrachloroauric acid is 0.9 mg/L (measured concentration) based on growth rate.

Value used for CSA:
EC50/LC50 for freshwater algae: 9 mg/L
EC10/LC10 or NOEC for freshwater algae: 0.9 mg/L

Additional information:
Data are available from a GLP-compliant study following OECD guideline 201, with a minor deviation in test media used due to potential for the standard media to interfere with the test item. A range-finding and definitive test were performed using 5 concentrations of test item. In the definitive test 3 replicates per concentration and 6 replicates for the control were tested. Results are reported based on measured and nominal concentrations (Brixham 2012b). This study is considered to be suitable for use as the key study for this endpoint. The EC50 for tetrachloroauric acid is reported to be >9.0 mg/L (measured concentration) based on growth rate and the NOEC is 0.9 mg/L.
Supporting data are available from a published guideline study for gold (III) chloride. Tests were conducted on two algae species with 5 test concentrations for 72 hours. Each treatment consisted of 6 to 11 replicates and results were reported as nominal concentrations (Nam et al. 2014). Effect concentrations were converted to tetrachloroauric acid concentrations on the basis of molecular weight. This study is considered to be suitable for use as a supporting study for this endpoint. The 72-hour IC50 and IC10 based on biomass were determined to be 3.52 mg/L tetrachloroauric acid (2.04 mg Au(III)/L) and 1.02 mg/L tetrachloroauric acid (0.59 mg Au(III)/L), respectively, for *P. subcapitata*. The NOEC for *P. subcapitata* was 1.73 mg/L tetrachloroauric acid. The IC50 for *E. gracili*s was 1.74 mg/L tetrachloroauric acid (1.01 mg Au(III)/L), based on biomass.
The acute toxicity of gold (III) chloride trihydrate to algae was also tested in a study according to the OECD 201 guideline (Garcia-Cambero 2013). The test was conducted with the test item at a range of test concentrations between 0.5 and 5 mg/L for 72 hours. This study is considered to be suitable for use as a supporting study for this endpoint. The 72-h EC50 was estimated to be 1.91 mg/L (1.30–2.83, 95% IC) for *Scenedesmus subspicatus*.

7.1.4. Sediment organisms

No relevant information available.

7.1.5. Other aquatic organisms

No relevant information available.

7.2. Terrestrial compartment

7.2.1. Toxicity to soil macro-organisms

No relevant information available.

7.2.2. Toxicity to terrestrial plants

No relevant information available.

7.2.3. Toxicity to soil micro-organisms

No relevant information available.

7.2.4. Toxicity to other terrestrial organisms

No relevant information available.

7.3. Microbiological activity in sewage treatment systems

The results are summarised in the following table:

Table 7.4. Effects on micro-organisms

Method	Results	Remarks
activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010]	NOEC (3h): 2 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate LOEC (3h): 6.4 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate EC50 (3h): 27.9 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate (15.0 - 33.3 mg/L, 95% confidence levels) EC20 (3h): 8.8 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate (2.5 - 14.7 mg/L, 95% confidence intervals) EC80 (3h): >50 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate	1 (reliable without restriction) key study experimental study **Test material** 16903-35-8 / 240-948-4, **Reference** Brixham Environmental Laboratory 2012c
other: *Escherichia coli* and *Bacillus subtilis* freshwater static according to The growth inhibition assay was performed according to the methodology of Kershaw et al. (2005), Kim et al. (2011, 2012), and Li et al. (2009). Study performed according to the methodology of Kershaw et al. (2005), Kim et al. (2011, 2012), and Li et al. (2009).	NOEC (12h): 17.25 mg/L test mat. - tetrachloroauric acid (nominal) based on: growth inhibition - (yield) (*B. subtilis*; effect concentrations reported based on Au(III), converted to tetrachloroauric acid, based on molecular weight.) NOEC (12h): 25.88 mg/L test mat. - tetrachloroauric acid (nominal) based on: growth inhibition - (yield) (*E.coli*; effect concentrations reported based on Au(III), converted to tetrachloroauric acid, based on molecular weight.) EC50 (12h): 31.4 mg/L test mat. - tetrachloroauric acid (nominal) based on: growth inhibition - (yield) (*B. subtilis*;	2 (reliable with restrictions) supporting study experimental study **Test material** gold (III) chloride, Form: solid: particulate/powder **Reference** Nam SH, Lee WM, Shin YJ, Yoon SJ, Kim SW,

	effect concentrations reported based on Au(III), converted to tetrachloroauric acid, based on molecular weight.) EC50 (12h): 24.5 mg/L test mat. - tetrachloroauric acid (nominal) based on: growth inhibition - (yield) (*E. coli*; effect concentrations reported based on Au(III), converted to tetrachloroauric acid, based on molecular weight.)	Kwak JI and An YJ 2014

Discussion

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:
The 3-hour EC50 based on respiration rate was 27.9 mg/L. The NOEC was 2 mg/L.

Value used for CSA:
EC50/LC50 for aquatic micro-organisms: 27.9 mg/L
EC10/LC10 or NOEC for aquatic micro-organisms: 2 mg/L

Additional information:
In a GLP-compliant study following OECD guideline 209, a range-finding test was carried out using 3 concentrations of test item, the highest concentration was tested in triplicate (Brixham 2012c). A definitive test was performed using 6 concentrations (5 replicates per test item) and a control. Results are reported as nominal concentrations. Although the validity criteria were not completely met this is not believed to have affected the study results. This study is therefore considered to be suitable for use for this endpoint. The 3-hour EC50 based on respiration rate was 27.9 mg/L. The NOEC was 2 mg/L.
Supporting data are available from a published guideline study for gold (III) chloride. Tests were conducted on two microorganism species with 5 test concentrations for 12 hours. Growth inhibition was determined based on biomass yield and results were reported as nominal concentrations (Nam et al. 2014). This study is considered to be suitable for use as a supporting study for this endpoint. Results reported in the study have been converted to concentrations of tetrachloroauric acid based on molecular weight. The 12-h EC50 was determined to be 24.5 mg/L tetrachloroauric acid (14.2 mg Au(III)/L) and 31.4 mg/L tetrachloroauric acid (18.2 mg Au(III)/L) for *E. coli* and *B. subtilis*, respectively.

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

7.4.1. Toxicity to birds

No relevant information available.

7.4.2. Toxicity to mammals

No relevant information available.

7.5. PNEC derivation and other hazard conclusions

Table 7.5. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 1.04 µg/L	Assessment factor: 1000 Extrapolation method: assessment factor The lowest valid short-term toxicity value is a 48-h EC50 of 1.04 mg TCA/L for *Daphnia magna*. The PNECfreshwater is derived based on a short-term 48-h EC50 of 1.04 mg TCA/L with a protective assessment factor of 1000.

	PNEC aqua (intermittent releases): 10.4 µg/L	PNEC intermittent release assessment factor: 100.0 PNEC intermittent release extrapolation method: assessment factor PNEC intermittent release justification: An assessment factor of 100 is applied on the lowest EC50 of the relevant available toxicity data (EC50 of 1.04 mg/L for *Daphna magna*).
Marine water	PNEC aqua (marine water): 0.104 µg/L	Assessment factor: 10000 Extrapolation method: assessment factor PNEC marine water is derived by applying an assessment factor of 10,000 on the lowest EC50 of the relevant available toxicity data (EC50 of 1.04 mg TCA/L for *Daphnia magna).*
Sediments (freshwater)	PNEC sediment (freshwater): 20.45 mg/kg sediment d.w.	Extrapolation method: equilibrium partitioning method The sediment PNEC is derived using equilibrium partitioning. A full justification is provided in the report attached.
Sediments (marine water)	PNEC sediment (marine water): 2.04mg/kg sediment d.w.	Extrapolation method: equilibrium partitioning method The sediment PNEC is derived using equilibrium partitioning. A full justification is provided in the report attached.
Sewage treatment plant	PNEC STP: 0.2 mg/L	Assessment factor: 10 Extrapolation method: assessment factor An assessment factor of 10 is applied to the 3-h NOEC of 2 mg TCA/L determined in an activated sludge respiration inhibition test.
Soil	PNEC soil: 4.15 mg/kg soil d.w.	Extrapolation method: equilibrium partitioning method The soil PNEC is derived using equilibrium partitioning. A full justification is provided in the report attached.
Air	no hazard identified	The test item it is considered to be not a precursor to ozone formation and is not expected to be a significant contribution to global warming. The test item is not an ozone depleting substance as defined by the Montreal Protocol and does not contain chemical constituents that would lead to acidification.
Secondary poisoning	no potential for bioaccumulation	No hazard is expected from secondary poisoning. A full justification is provided in the report attached.

Conclusion on environmental classification

Acute aquatic data are available for three trophic levels for the test item. The most sensitive endpoint was determined to be *Daphnia*, with a 48-hour EC50 of 1.04 mg/L (Nam et al. 2014). As this result is >1 mg/L, no acute classification is assigned to this substance. Chronic toxicity data are only available for algae. A 72-h NOEC of 0.9 mg TCA/L is reported from an algal growth inhibition study with *Pseudokirchneriella subcapitata* (Brixham 2012b). The test item is highly soluble in water with solubility of >1067 g/L and the chronic toxicity result for the most sensitive trophic level is >0.1 ≤ 1 mg/L, therefore the test item is classified as hazardous to the aquatic environment with Category Chronic 2. Since chronic data is available only for algae for the test item, classification with both the acute and chronic data must be considered, and the substance classified according to the most

stringent outcome. Based on acute toxicity data >1 to ≤ 10 mg/L, the test item is also classified as Chronic Category 2.
Tetrachloroauric acid is classified for the environment as Chronic Category 2.

General discussion

PNECs were derived based on test data following standard guidelines. All data are considered to be reliable and relevant for the endpoint concerned.
Short-term aquatic data in freshwater are available for three trophic levels for the test item. The most sensitive endpoint was determined to be *Daphnia*, with a 48 -hour EC50 of 1.04 mg/L (Nam et al. 2014). This endpoint was used to derive the PNECs for freshwater, marine water and intermittent releases by assessment factor method, and freshwater sediment, marine sediment and soil by equilibrium partitioning approach.
For derivation of the PNEC for STP, the NOEC of 2 mg/L was taken from the 3-hour respiration inhibition test (Brixham 2012c). A PNEC of 0.2 mg/L was derived by applying an assessment factor of 10.
The test item it is not considered to be a precursor to ozone formation and is not expected to be a significant contribution to global warming. The test item is not an ozone depleting substance as defined by the Montreal Protocol and does not contain chemical constituents that would lead to acidification.
No hazard is expected from secondary poisoning.

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. PBT/vPvB criteria and justification

8.1.2. Summary and overall conclusions on PBT or vPvB properties

Overall conclusion: PBT assessment does not apply.

Justification: Tetrachloroauric acid is an inorganic and therefore the PBT assessment is unjustified.

8.2. Emission characterisation

9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.0. Introduction

9.0.1. Overview of uses and Exposure Scenarios

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

CLEANING AND MAINTENANCE
Worker contributing scenarios (CS) for cleaning and maintenance tasks are included for the manufacturing and formulation stage and for industrial uses. For the professional use, separate worker CS for cleaning and maintenance activities are not considered to be required for the following reasoning: during a professional use of the substance, the availability of local exhaust ventilation is relatively rare and therefore, some worst-case tasks during cleaning, i.e. exchange of LEV filters, are not conducted and exposure during the process itself is considered to result in highest exposure levels that cover exposure during cleaning and maintenance tasks.

9.0.2. Assessment entity groups

Not applicable

9.0.3. Introduction to the assessment for the environment

9.0.3.1 Methodology – environmental exposure

Assessment has been undertaken of risks posed to all relevant environmental compartments by releases of tetrachloroauric acid (TCA) during the manufacture and use of TCA. Environmental risk assessment has been based on measured emission data, where available, metal industry SpERCs[1], ERCs and estimation of environmental concentrations based on algorithms taken from ECHA technical guidance [2]. Risk characterisation is performed by comparison of the 'predicted environmental concentrations' (PECs) to appropriate 'predicted no effect concentrations' (PNECs) derived from ecotoxicological testing.

Exposure estimates are based primarily on the release factors (RFs) detailed in default and Sector-specific Environmental Release Categories (ERCs and SpERCs, respectively) (supported by monitoring data for measured gold concentrations in emissions at production facilities), supplemented by modelling based on the recommendations of ECHA's technical guidance on exposure assessment for REACH registration. The selected environmental GES parameter values have been used to calculate the maximum safe tonnage (Msafe) of TCA that can be manufactured without posing an unacceptable risk to the environment.

Table 9.1. Parameter values for generic exposure scenarios

	Waste-water discharge				Stack emissions to air	
GES	**Release factor (g/T)**	**Emission days**	**STP flow rate (m^3/d)**	**Receiving water flow rate**	**Release factor (g/T)**	**Emission days**
ES 1 Manufacture &	200	300	2,000		30	300

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

[2] ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 2.1, October 2012)

ES 3 Intermediate	(10% SpERC RF)		(TGD default)		(10% SpERC RF)	
ES 2 and 4 Formulation	200 (1% pre-WWTP SpERC RF)	300			10 (10% SpERC RF)	300
ES 5 Industrial production of imaging and printing articles, ES 6 Industrial production of printing plates, ES 7 Industrial application of imaging and printing chemicals & ES 9 Industrial use in electrochemical and galvanic plating	500 (10% SpERC RF)	220		18,000 (TGD default)	200 (10% SpERC RF)	220
ES 8 Professional use in photographic applications	30,000 (10% ERC)	220			15,000 (10% ERC)	220
ES 10 Professional Surface Treatment	30,000 (10% ERC)	220			15,000 (10% ERC)	220

Environmental releases were estimated using adjusted values from the relevant ERCs and SpERCs[1]. The release factors detailed in the SpERCs are based on measured emissions from sites producing or using base metals such nickel, tin and zinc. Due to the considerably higher monetary value of gold it is considered that emissions from the manufacture and use TCA are likely to be at least an order of magnitude lower and release factors for water and air from the SpERC have been adjusted accordingly. Emissions of TCA to water and air based on RFs taken from the SpERC documents or default ERCs have been adjusted to 10% of the recommended value (with the exception of adjustment to the waste-water RF for formulation which is discussed in ES 2).

9.0.3.2 Methodology – indirect exposure via the environment

Assessment of the risk posed to man via environmental emissions is focussed on inhalation exposure following stack emissions to the atmosphere and their subsequent dispersal, which may lead to exposure of the general population living downwind of emissions. Releases to the atmosphere during the manufacture of TCA and its subsequent downstream uses are estimated based on the release factors detailed in the relevant ERCs and metal sector SpERCs (adjusted to 10% based on monetary value of gold) and its application to the Msafe tonnage. Use of adjusted RFs is supported by a limited amount of data on measured stack emissions for manufacture of TCA. Exposure to the general population is estimated based on the quantity emitted to the atmosphere and use of an algorithm taken from ECHA technical guidance. Risk characterisation is performed by comparison of the estimated airborne concentration to a ‘derived no effect level’ (DNEL) for the general population.

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 9.2. 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) = 0.14 mg/m³
	Systemic effects - acute	Qualitative	HAZ_ASSESS_UNKNOWN_BUT_NOT_NECESSARY
	Local effects - long term	Qualitative	High hazard (no threshold derived)
	Local effects - acute	Qualitative	High hazard (no threshold derived)
Dermal	Systemic effects - long term	Quantitative	DNEL (Derived No Effect Level) = 0.04 mg/kg bw/day
	Systemic effects - acute	Qualitative	HAZ_ASSESS_UNKNOWN_BUT_NOT_NECESSARY
	Local effects - long term	Qualitative	High hazard (no threshold derived)
	Local effects - acute	Qualitative	High hazard (no threshold derived)
Eye	Local effects	Qualitative	High 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 precious metals industry, good occupational hygiene practices are followed to ensure safe handling of precious metals. 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 ACUTE SYSTEMIC EFFECTS VIA INHALATION AND VIA THE DERMAL ROUTE

According to industry information, acute systemic effects via inhalation and the dermal route are protected for by the long-term DNEL together with CLP skin and eye classifications that involve precautionary measures to protect for local effects that would intrinsically reduce systemic uptake. The risk of acute systemic effects via inhalation is therefore adequately controlled.

QUALITATIVE RISK CHARACTERISATION FOR LOCAL EFFECTS

In addition to the quantitative risk characterisation, demonstrating that prescribed operational conditions and risk management measures effectively control exposure well below the respective DNELs, residual exposure concentrations may theoretically still cause local effects. As a precautionary measure, it is therefore prescribed to use personal protective equipment in situations in which such residual exposure concentrations cannot be excluded. The risk of local effects is therefore adequately controlled.

MODELLED EXPOSURE

Occupational exposure was assessed with the aid of the MEASE tool (version, 1.02.01, available on http://www.ebrc.de/mease.html). All parameters needed to re-run the tool are provided in the respective exposure scenarios. Further information on input parameters can be found in the glossary of the tool. Due to Industry information, the solid form of tetrachloroauric acid is of significant hygroscopic nature leading to a very low emission potential during handling of the substance. Based on this, the dustiness of the solid substance is categorised in MEASE to be very low by using "Massive object" as a surrogate value. It is noted that for assessments of uses, for which the physical form "liquid" have been reported, the physical form "aqueous solution" has been selected in MEASE as a surrogate value. For the assessment of dermal exposure, the categories "pattern of use" and "pattern of exposure control" are the most important parameters, in addition the "contact level" was indicated in some instances if required. Generally, a distinction of direct or non-direct handling for the pattern of exposure control was made depending on the level of automation and enclosure of a process. The contact level is based on the anticipated number of contacts with the substance in a shift, applied where required.

General information on risk management related to toxicological hazard:

GENERAL INFORMATION RELATED TO PERSONAL PROTECTIVE EQUIPMENT FOR WORKERS

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

DERMAL ROUTE (SKIN PROTECTION)

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

INHALATION ROUTE (RESPIRATORY PROTECTION)

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

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

9.0.5. Introduction to the assessment for consumers

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

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

Environment contributing scenario(s):		
CS 1	Manufacture of the substance (as such)	ERC 1
Worker contributing scenario(s):		
CS 2	Chemical reaction and further processing in closed process	PROC 1
CS 3	Chemical reaction and further processing in closed continuous process	PROC 2
CS 4	Chemical reaction and further processing in closed batch process	PROC 3
CS 5	Evaporation	PROC 3
CS 6	Liquid based granulation	PROC 4
CS 7	Liquid-based granulation	PROC 5
CS 8	Laboratory analyses of liquid substance	PROC 15
CS 9	Laboratory analyses of solid substance	PROC 15
CS 10	Handling of liquid substance at non-dedicated facilities	PROC 8a
CS 11	Handling of liquid substance	PROC 8b
CS 12	Small scale handling of liquid substance	PROC 9
CS 13	Handling and transfer of solid substance	PROC 21
CS 14	Wet cleaning	PROC 28
CS 15	Vacuum cleaning	PROC 28

Explanation on the approach taken for the ES

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

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

9.1.1.1. Conditions of use

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

9.1.1.2. Releases

The GES and associated risk assessment are concerned with releases of TCA to waste-water and air arising from the manufacture of TCA. Waste-water is treated by an on-site waste-water treatment plant (WWTP) and at a municipal sewage treatment plant (STP) before discharge to freshwater. Airborne emissions are treated by in-stack mitigation systems prior to discharge. Exposure assessment for the environment is based on representative exposure characteristics from the TCA manufacturing sector, adjusted SpERC values and calculation of the maximum safe tonnage (Msafe) of TCA that can be manufactured without risk to the environment. Msafe is calculated using release factors adjusted to

10% of the values recommended in SpERCs on the basis of the monetary value of gold (see Section 9.0.2).

Data on environmental emissions of gold during manufacture of TCA were collected during 2015 from 5 sites across Europe. A very limited amount monitoring data are available and it should be noted these are based on emissions of total gold, often resulting from production and use of a variety of gold compounds. The use of adjusted release factors is supported by the available data on measured Au emissions in waste-water at sites producing TCA. In this assessment the release factor (RF) is set at 10% of the SpERC RF for 'manufacture of metal compounds'[3]. For a substance with Kd of 10,000-25,000 L/kg for suspended matter the recommend RF is 0.2%. In this assessment the RF for TCA (Kd = 19,904 L/kg for suspended particulate matter) is set at 0.02% (equivalent to 200 g/T). The maximum reported RF based on site emission measurements at facilities producing TCA is 11.5 g/T, indicating that even use of the adjusted SpERC could be considered worst case, although only 2 sites reported data on emissions of Au or TCA in waste-water. Similarly, a 10% adjusted RF to air of 0.03% (adjusted from 0.3% and equivalent to 30 g/T) is much higher than the only available RF of 0.4 g/T based on measurements from one site manufacturing TCA.

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for manufacture of TCA is detailed below.

Table 9.3 The generic exposure scenario (GES) for manufacture of TCA

1. Title **ES1: Manufacture of TCA**	
Life cycle	Manufacture - Manufacture of the substance (as such)
Systematic title based on use descriptor	**ERC:** ERC 1 Manufacture of substances
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Production of TCA
Systematic title based on use descriptor (environment)	ERC 1 Manufacture of substances
Processes, tasks, activities covered (environment)	Production of TCA: Raw material delivery and handling, production and processing of TCA, packaging of TCA, cleaning & maintenance.
Environmental Assessment Method	Estimates based on monitoring data of emissions are used for calculation of maximum tonnage that can be manufactured or used safely without risk to the environment
Product characteristics TCA as solid or aqueous solution. Environmental assessment is based on the estimated emission of TCA in waste-water discharge and in stack emissions to air.	
Amounts used	
Maximum annual safe production/use at a site (Msafe)	30 tonnes TCA (17.4 tonnes Au metal equivalent)
Frequency and duration of use	

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

Pattern of release to the environment	300 days per year per site (50P from sector data)
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default) Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	Not relevant
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: ES 1 Discharge to freshwater via STP: On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99.8 % (sector data) Release factor after on-site treatment: 200 g/T (10% of SpERC RF for 'Manufacture of metal compounds'[4] based on TCA Kd of 19,904 L/kg) and off-site municipal sewage treatment plant (STP) Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon) **Air:** Treatment of air emissions by filters (e.g. fabric, bag, HEPA) and/or wet scrubbers. Release factor after on-site treatment: 30 g/T (10% of SpERC RF for 'Manufacture of metal compounds'[5])	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	
Municipal Sewage Treatment Plant (STP)	Yes,
Discharge rate of the Municipal STP	2 000 m^3/d (default)
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)
Conditions and measures related to external treatment of waste for disposal	
TCA- and other Au-containing waste is filled into containers and transported to licensed recycling facilities for recovery or disposed of at appropriate landfill facilities.	
Conditions and measures related to external recovery of waste	

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

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

TCA- and other Au-containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.

The sludge from the on-site treatment plant is processed for metal reclamation (recycling).

3. Exposure and risk estimation

Environment

ERC 1

ES 1 Production of TCA

Compartment	**Unit**	**PNEC**	**$PEC_{regional}$**	**C_{local}**	**PEC**	**RCR**	**Methods for calculation of environmental concentrations**
Discharge to STP	mg TCA/L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.1 x 10^{-3} mg/L	1.1 x 10^{-3} mg/L	0.0056	Adjusted SpERC emission factors applied to Msafe tonnage and dilution factor at municipal STP
Freshwater via STP	mg TCA/L	1.04 $x10^{-3}$ mg/L	2.05 $x10^{-7}$ mg/L	8.63 $x10^{-5}$ mg/L	8.65 $x10^{-5}$ mg/L	0.083	Adjusted SpERC emission factors applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/kg w.w.	4.5 mg/kg	4.11 $x10^{-4}$ mg/kg	0.374 mg/kg	0.375 mg/kg	0.83	Adjusted SpERC emission factors applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.
Terrestrial (all scenarios)	mg TCA/kg ww	3.65 mg/kg	1.89 $x10^{-3}$ mg/kg	1.8 $x10^{-6}$ mg/kg	1.89 $x10^{-3}$ mg/kg	0.0005	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES
Environment Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool) Scaling of the release to air and water environment includes: • Refining of the release factor to air and waste water and/or and the efficiency of the air filter and wastewater treatment facility. • Adjustment of the flow rate for the receiving water body and subsequent dilution factor.

9.1.1.3. Exposure and risks for man via the environment

Assessment of risks for man via the environment is based on inhalation exposure to airborne particulates containing TCA released to the atmosphere during the manufacture of TCA.

Table 9.4 Exposure and risks for man via the environment

Annual emission to air (kg TCA)	Emission days per year	Concentration in local air (mg TCA/m^3)	Annual average concentration in air (mg TCA/m^3)	DNEL (mg TCA/m^3)	RCR
0.90	300	8.3 $x10^{-7}$	6.9 $x10^{-7}$	0.007	1.2 $x10^{-4}$

9.1.2. Worker CS 2: Chemical reaction and further processing in closed process (PROC 1)

9.1.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed process without likelihood of exposure • Level of automation: Fully automated process • Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] *Standard efficiency* • Pattern of use: Closed system without breaches • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*
Other conditions affecting workers exposure
• Process temperature is always kept below 130 °C.

9.1.2.2. Exposure and risks for workers

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

Table 9.5. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	1E-3 mg/m³ (MEASE: 1.02.01)	RCR < 0.01
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.05

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in

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

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.3. Worker CS 3: Chemical reaction and further processing in closed continuous process (PROC 2)

9.1.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed continuous process with occasional controlled exposure • Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] *Standard efficiency* • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*
Other conditions affecting workers exposure
• Process temperature is always kept below 130 °C.

9.1.3.2. Exposure and risks for workers

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

Table 9.6. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	1E-3 mg/m³ (MEASE: 1.02.01)	RCR < 0.01
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075

Route of exposure and type of effects	Exposure concentration	Risk quantification
Combined routes, systemic, long-term		RCR = 0.082

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.4. Worker CS 4: Chemical reaction and further processing in closed batch process (PROC 3)

9.1.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed batch process with occasional controlled exposure • Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] *Standard efficiency* • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*
Other conditions affecting workers exposure
• Process temperature is always kept below 130 °C.

9.1.4.2. Exposure and risks for workers

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

Table 9.7. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	2E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.014
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.057

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.5. Worker CS 5: Evaporation (PROC 3)

9.1.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed batch process with occasional controlled exposure • Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] *Standard efficiency* • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes

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.
Other conditions affecting workers exposure
• Process temperature is always kept below 130 °C.

9.1.5.2. Exposure and risks for workers

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

Table 9.8. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	2E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.014
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.057

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.6. Worker CS 6: Liquid based granulation (PROC 4)

9.1.6.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Level of containment: Semi-closed process • Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] *Standard efficiency* • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation

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. • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*
Other conditions affecting workers exposure
• Process temperature is always kept below 130 °C.

9.1.6.2. Exposure and risks for workers

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

Table 9.9. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.011 mg/m³ (MEASE: 1.02.01)	RCR = 0.079
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.154

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.7. Worker CS 7: Liquid-based granulation (PROC 5)

9.1.7.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] *Standard efficiency* • Pattern of use: Non-dispersive use

• Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*
Other conditions affecting workers exposure
• Process temperature is always kept below 130 °C.

9.1.7.2. Exposure and risks for workers

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

Table 9.10. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.011 mg/m³ (MEASE: 1.02.01)	RCR = 0.079
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.154

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.8. Worker CS 8: Laboratory analyses of liquid substance (PROC 15)

Task(s) covered with this contributing scenario: Quality control, sampling.

9.1.8.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] *Standard efficiency* • Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.1.8.2. 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	2E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.014
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.057

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.9. Worker CS 9: Laboratory analyses of solid substance (PROC 15)

Task(s) covered with this contributing scenario: Quality control, sampling.

9.1.9.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Solid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] *Standard efficiency* • Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.1.9.2. 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	2E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.014
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.057

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.10. Worker CS 10: Handling of liquid substance at non-dedicated facilities (PROC 8a)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.1.10.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.1.10.2. 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	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.11. Worker CS 11: Handling of liquid substance (PROC 8b)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.1.11.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] *Standard efficiency* • Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.1.11.2. 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	2E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.014
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75
Combined routes, systemic, long-term		RCR = 0.764

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.12. Worker CS 12: Small scale handling of liquid substance (PROC 9)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.1.12.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] *Standard efficiency* • Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.1.12.2. 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	2E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.014
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75
Combined routes, systemic, long-term		RCR = 0.764

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation

and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.13. Worker CS 13: Handling and transfer of solid substance (PROC 21, PROC 26)

9.1.13.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Solid • Maximum emission potential of the substance: 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: 15 - 60 min [Effectiveness Inhalation: 80%, Dermal: 80%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] *Standard efficiency* • Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.1.13.2. 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	7E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.05
Dermal, systemic, long term	0.028 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.7
Combined routes, systemic, long-term		RCR = 0.75

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.14. Worker CS 14: Wet cleaning (PROC 28)

9.1.14.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.1.14.2. 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	5E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.036
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75

Route of exposure and type of effects	Exposure concentration	Risk quantification
Combined routes, systemic, long-term		RCR = 0.786

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 8a was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of dermal 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

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.1.15. Worker CS 15: Vacuum cleaning (PROC 28)

9.1.15.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Solid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] *Surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner.* • Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.1.15.2. 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	8E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.057
Dermal, systemic, long term	0.014 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.35
Combined routes, systemic, long-term		RCR = 0.407

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 21 was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in table.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.2. Exposure scenario 2: Formulation or re-packing - Formulation

Market sector: Formulation
Product category formulated: PC 20: Products such as ph-regulators, flocculants, precipitants, neutralization agents

Environment contributing scenario(s):		
CS 1	Formulation	ERC 2
Worker contributing scenario(s):		
CS 2	Handling and packaging of liquid substance	PROC 8b
CS 3	Small scale handling and packaging of liquid substance	PROC 9
CS 4	Handling and transfer of solid substance	PROC 21
CS 5	Formulation in open or semi-closed process of solid substance	PROC 4
CS 6	Mixing or blending in batch process of liquid substance	PROC 5
CS 7	Wet cleaning	PROC 28
CS 8	Vacuum cleaning	PROC 28

Explanation on the approach taken for the ES

9.2.1. Env CS 1: Formulation (ERC 2)

9.2.1.1. Conditions of use

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

9.2.1.2. Releases

The GES and associated risk assessment are concerned with releases of TCA to waste-water and air occurring during the formulation of TCA at an industrial facility. This waste-water is discharged to freshwater following treatment at a municipal STP. Exposure assessment for the aquatic environment is based on parameter values from the SpERC for formulation of metal compounds[6] ('formulation of metal compounds in other than plastics and paint sectors') and calculation of the maximum tonnage (Msafe) of TCA that can be formulated without risk to the environment. The release factor for waste-water in this SpERC is given as '2% before on-site treatment'. However, all sites formulating TCA will have waste-water treatment plants (WWTPs), predominantly using pH adjustment and precipitation. The Msafe tonnage for formulation is therefore calculated using a release factor (RF) adjusted to include a WWTP efficiency of 99% (i.e. the RF for water is reduced from 2% to 0.02%).

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for formulation of TCA is detailed in the table below .

Table 9.19. The generic exposure scenario (GES) for formulation of TCA

1. Title **ES2: Formulation**	
Life cycle	Formulation - Formulation
Systematic title based on use descriptor	**ERC:** ERC 2 Formulation of preparations containing TCA
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Formulation
Systematic title based on use descriptor (environment)	ERC 2 Formulation of preparations
Processes, tasks, activities covered (environment)	Formulation: delivery, mixing, dissolving and packaging
Environmental Assessment Method	Estimates based on adjusted SpERC RFs are used for calculation of the maximum tonnage that can be safely used without risk to the environment
Product characteristics TCA as solid or aqueous solution. Environmental assessment is based on the modelled emission of TCA in waste-water discharge and TCA emissions to air.	
Amounts used	
Maximum annual safe use at a site (Msafe)	30 tonnes TCA (17.4 tonnes Au metal equivalent)
Frequency and duration of use	
Pattern of release to the environment	300 days per year per site (standard for sector; see ES1)
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default)

[6] http://www.arche-consulting.be/content/documents/Eurometaux-2.2a-c.v2.1.pdf

	Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	Not relevant
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: ES 2 Discharge to freshwater via STP: On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency >99 % (chemical precipitation; SpERC for 'Formulation of metal compounds') and off-site municipal sewage treatment plant (STP) Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon) Release factor after on-site treatment: 200 g/T (99% treatment WWTP efficiency applied to 2% RF before on-site treatment) **Air:** Treatment of air emissions by filters, electrostatic precipitation and/or wet scrubbers.(SpERC for 'Formulation of metal compounds') Release factor after on-site treatment: 10 g/T (10% of SpERC RF for air)	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	
Municipal Sewage Treatment Plant (STP)	Yes
Discharge rate of the Municipal STP	2 000 m^3/d
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)
Conditions and measures related to external treatment of waste for disposal	
TCA- and other Au-containing waste is filled into containers and transported to licensed recycling facilities for recovery or disposed of at landfill.	
Conditions and measures related to external recovery of waste	
TCA- and other Au-containing waste suitable for recycling may be recycled either internally or at licensed recycling facility. The sludge from the on-site treatment plant is processed for metal reclamation (recycling).	
3. Exposure and risk estimation	

Environment

ERC 2

ES 2 Formulation of TCA

Compartment	Unit	PNEC	$PEC_{regional}$	C_{local}	PEC	RCR	Methods for calculation of environmental concentrations
Discharge to STP	mg TCA/L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.1 x 10^{-3} mg/L	1.1 x 10^{-3} mg/L	0.0057	Adjusted SpERC emission factors applied to Msafe tonnage and dilution factor at municipal STP
Freshwater via STP	mg TCA/L	1.04 $x10^{-3}$ mg/L	2.05 $x10^{-7}$ mg/L	8.70 $x10^{-6}$ mg/L	8.91 $x10^{-6}$ mg/L	0.0086	Adjusted SpERC emission factors applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/kg w.w.	4.5 mg/kg	4.11 $x10^{-4}$ mg/kg	0.039 mg/kg	0.039 mg/kg	0.087	Adjusted SpERC emission factors applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.
Terrestrial (all scenarios)	mg TCA/kg w.w.	3.65 mg/kg	1.89 $x10^{-3}$ mg/kg	6.00 $x10^{-7}$ mg/kg	1.89 $x10^{-3}$ mg/kg	0.0005	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)

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

Environment

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

Scaling of the release to air and water environment includes:

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

9.2.1.3. Exposure and risks for man via the environment

Assessment of risks for man via the environment is based on inhalation exposure to airborne particulates containing TCA released to the atmosphere during the formulation of TCA and other TCA compounds.

Table 9.20. Exposure and risks for man via the environment

Annual emission to air (kg TCA)	Emission days per year	Concentration in local air (mg TCA/m^3)	Annual average concentration in air (mg TCA/m^3)	DNEL (mg TCA/m^3)	RCR
0.3	300	2.8 x10^{-7}	2.3 x10^{-7}	0.007	4.0 x10^{-5}

9.2.2. Worker CS 2: Handling and packaging of liquid substance (PROC 8b)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.2.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*

9.2.2.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.2.3. Worker CS 3: Small scale handling and packaging of liquid substance (PROC 9)

Task(s) covered with this contributing scenario: Small scale transfer and filling process.

9.2.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*

9.2.3.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.2.4. Worker CS 4: Handling and transfer of solid substance (PROC 21)

9.2.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Solid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*

9.2.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (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	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	0.014 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.35
Combined routes, systemic, long-term		RCR = 0.707

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.2.5. Worker CS 5: Formulation in open or semi-closed process of solid substance (PROC 4)

Task(s) covered with this contributing scenario: Mixing, blending of tetrachloroauric acid.

9.2.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Solid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374*

have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.

9.2.5.2. Exposure and risks for workers

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

Table 9.24. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.2.6. Worker CS 6: Mixing or blending in batch process of liquid substance (PROC 5)

9.2.6.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*

9.2.6.2. Exposure and risks for workers

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

Table 9.25. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.2.7. Worker CS 7: Wet cleaning (PROC 28)

9.2.7.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.*

9.2.7.2. 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	5E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.036
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75
Combined routes, systemic, long-term		RCR = 0.786

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 8a was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of dermal 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

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.2.8. Worker CS 8: Vacuum cleaning (PROC 28)

9.2.8.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Solid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Integrated local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 84%] *Surrogate exposure determinant used to reflect the efficiency of a vacuum cleaner.* • Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.
• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%]
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes
Due to the adverse effects of the substance to the eyes, direct contact of the eyes with the substance is to be avoided including hand to eye transfer after touching contaminated surfaces. Suitable eye protection equipment (e.g. goggles or visors) must be worn.

9.2.8.2. 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	8E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.057
Dermal, systemic, long term	0.014 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.35
Combined routes, systemic, long-term		RCR = 0.407

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 21 was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3. Exposure scenario 3: Use at industrial sites - Use as an intermediate

Market sector: Manufacture of other substances
Sector of use: SU 14: Manufacture of basic metals, including alloys; SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals

Environment contributing scenario(s):		
CS 1	Use as an intermediate	ERC 6a
Worker contributing scenario(s):		
CS 2	Handling of liquid substance at non-dedicated facilities	PROC 8a
CS 3	Handling of liquid substance	PROC 8b
CS 4	Small scale handling of liquid substance	PROC 9
CS 5	Chemical reaction step in closed process	PROC 1
CS 6	Chemical reaction step in closed continuous process	PROC 2
CS 7	Chemical reaction step in closed batch process	PROC 3
CS 8	Chemical reaction step in open or semi-closed process	PROC 4
CS 9	Mixing or blending in batch process	PROC 5
CS 10	Laboratory analyses	PROC 15

CS 11	Production of metal powders in wet process	PROC 27b
CS 12	Wet cleaning	PROC 28

Explanation on the approach taken for the ES

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

9.3.1. Env CS 1: Use as an intermediate (ERC 6a)

9.3.1.1. Conditions of use

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

9.3.1.2. Releases

The GES and associated risk assessment are concerned with releases of TCA to waste-water and air arising from the use of TCA as an intermediate. Waste-water is treated by an on-site waste-water treatment plant (WWTP) and at a municipal sewage treatment plant (STP) before discharge to freshwater. Airborne emissions are treated by in-stack mitigation systems prior to discharge. Exposure assessment for the environment is based on representative exposure characteristics from the TCA manufacturing sector, adjusted SpERC values and calculation of the maximum safe tonnage (Msafe) of TCA that can be manufactured without risk to the environment. Msafe is calculated using release factors adjusted to 10% of the values recommended in SpERCs on the basis of the monetary value of gold (see Section 9.0.2).

Data on environmental emissions of gold during manufacture of TCA were collected during 2015 from 5 sites across Europe. A very limited amount monitoring data are available and it should be noted these are based on emissions of total gold, often resulting from production and use of a variety of gold compounds. The use of adjusted release factors is supported by the available data on measured Au emissions in waste-water at sites producing TCA. In this assessment the release factor (RF) is set at 10% of the SpERC RF for 'manufacture of metal compounds'[7]. For a substance with Kd of 10,000-25,000 L/kg for suspended matter the recommend RF is 0.2%. In this assessment the RF for TCA (Kd = 19,904 L/kg for suspended particulate matter) is set at 0.02% (equivalent to 200 g/T). The maximum reported RF based on site emission measurements at facilities producing TCA is 11.5 g/T, indicating that even use of the adjusted SpERC could be considered worst case, although only 2 sites reported data on emissions of Au or TCA in waste-water. Similarly, a 10% adjusted RF to air of 0.03% (adjusted from 0.3% and equivalent to 30 g/T) is much higher than the only available RF of 0.4 g/T based on measurements from one site manufacturing TCA.

The use of TCA as an industrial intermediate is considered to have the same operating conditions and emission characteristics as manufacture on the basis that many companies in this sector manufacture TCA for use as an intermediate and using facilities using this compounds as intermediate would be undertaking similar processes.

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for industrial use of TCA as used as an intermediate is detailed below.

Table 9.28. The generic exposure scenario (GES) for industrial use of TCA as used as an intermediate

1. Title
ES3: Industrial use as intermediate

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

Life cycle	Industrial use as intermediate
Systematic title based on use descriptor	**ERC:** ERC 6A Use as an intermediate – industrial
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Use as an industrial intermediate
Systematic title based on use descriptor (environment)	ERC 6A Use as an intermediate – industrial
Processes, tasks, activities covered (environment)	Use as an industrial intermediate: delivery and processing of TCA, cleaning & maintenance.
Environmental Assessment Method	Estimates based on monitoring data of emissions are used for calculation of maximum tonnage that can be manufactured or used safely without risk to the environment
Product characteristics TCA as solid or aqueous solution. Environmental assessment is based on the estimated emission of TCA in waste-water discharge and in stack emissions to air.	
Amounts used	
Maximum annual safe production/use at a site (Msafe)	30 tonnes TCA (17.4 tonnes Au metal equivalent)
Frequency and duration of use	
Pattern of release to the environment	300 days per year per site (50P from sector data)
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default) Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	Not relevant
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: ES 1 Discharge to freshwater via STP: On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency 99.8 % (sector data) Release factor after on-site treatment: 200 g/T (10% of SpERC RF for 'Manufacture of metal compounds'[8] based on TCA Kd of 19,904 L/kg)	

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

and off-site municipal sewage treatment plant (STP)

Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon)

Air:

Treatment of air emissions by filters (e.g. fabric, bag, HEPA) and/or wet scrubbers.

Release factor after on-site treatment: 30 g/T (10% of SpERC RF for 'Manufacture of metal compounds'[9])

Organizational measures to prevent/limit release from site

Regular operator training.

Conditions and measures related to municipal sewage treatment plant (if applicable)

Municipal Sewage Treatment Plant (STP)	Yes,
Discharge rate of the Municipal STP	2 000 m^3/d (default)
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)

Conditions and measures related to external treatment of waste for disposal

TCA- and other Au-containing waste is filled into containers and transported to licensed recycling facilities for recovery or disposed of at appropriate landfill facilities.

Conditions and measures related to external recovery of waste

TCA- and other Au-containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.

The sludge from the on-site treatment plant is processed for metal reclamation (recycling).

3. Exposure and risk estimation

Environment

ERC 6A

ES 3 Use of TCA as an industrial intermediate

Compartment	**Unit**	**PNEC**	**$PEC_{regional}$**	**C_{local}**	**PEC**	**RCR**	**Methods for calculation of environmental concentrations**
Discharge to STP	mg TCA/L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.1 x 10^{-3} mg/L	1.1 x 10^{-3} mg/L	0.0056	Adjusted SpERC emission factors applied to Msafe tonnage and dilution factor at municipal STP

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

Freshwater via STP	mg TCA/L	1.04 x10^{-3} mg/L	2.05 x10^{-7} mg/L	8.63 x10^{-5} mg/L	8.65 x10^{-5} mg/L	0.083	Adjusted SpERC emission factors applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/kg w.w.	4.5 mg/kg	4.11 x10^{-4} mg/kg	0.374 mg/kg	0.375 mg/kg	0.83	Adjusted SpERC emission factors applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.
Terrestrial (all scenarios)	mg TCA/kg ww	3.65 mg/kg	1.89 x10^{-3} mg/kg	1.8 x10^{-6} mg/kg	1.89 x10^{-3} mg/kg	0.0005	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)

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

Environment

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

Scaling of the release to air and water environment includes:

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

9.3.1.3. Exposure and risks for man via the environment

Assessment of risks for man via the environment is based on inhalation exposure to airborne particulates containing TCA released to the atmosphere during the manufacture of TCA.

Table 9.29. Exposure and risks for man via the environment

Annual emission to air (kg TCA)	Emission days per year	Concentration in local air (mg TCA/m^3)	Annual average concentration in air (mg TCA/m^3)	DNEL (mg TCA/m^3)	RCR

0.90	300	8.3 x10^{-7}	6.9 x10^{-7}	0.007	1.2 x10^{-4}

9.3.2. Worker CS 2: Handling of liquid substance at non-dedicated facilities (PROC 8a)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.3.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.3.2.2. 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	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.3. Worker CS 3: Handling of liquid substance (PROC 8b)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.3.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.3.3.2. Exposure and risks for workers

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

Table 9.31. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.4. Worker CS 4: Small scale handling of liquid substance (PROC 9)

Task(s) covered with this contributing scenario: Small scale transfer and filling process.

9.3.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.3.4.2. Exposure and risks for workers

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

Table 9.32. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.

Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.5. Worker CS 5: Chemical reaction step in closed process (PROC 1)

9.3.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed process without likelihood of exposure • Level of automation: Fully automated process • Pattern of use: Closed system without breaches • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*
Other conditions affecting workers exposure
• Elevated temperature possible

9.3.5.2. Exposure and risks for workers

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

Table 9.33. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	1E-3 mg/m³ (MEASE: 1.02.01)	RCR < 0.01
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.05

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in

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

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.6. Worker CS 6: Chemical reaction step in closed continuous process (PROC 2)

9.3.6.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed continuous process with occasional controlled exposure • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*

9.3.6.2. Exposure and risks for workers

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

Table 9.34. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	1E-3 mg/m³ (MEASE: 1.02.01)	RCR < 0.01
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.082

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term

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

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.7. Worker CS 7: Chemical reaction step in closed batch process (PROC 3)

9.3.7.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed batch process with occasional controlled exposure • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.3.7.2. Exposure and risks for workers

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

Table 9.35. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.114

Remarks on exposure data from external estimation tools:

MEASE 1.02.01

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

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.8. Worker CS 8: Chemical reaction step in open or semi-closed process (PROC 4)

9.3.8.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.3.8.2. Exposure and risks for workers

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

Table 9.36. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01

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

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.9. Worker CS 9: Mixing or blending in batch process (PROC 5)

9.3.9.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.3.9.2. 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	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term

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

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.10. Worker CS 10: Laboratory analyses (PROC 15)

Task(s) covered with this contributing scenario: Quality control, sampling.

9.3.10.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.3.10.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.114

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term

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

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.11. Worker CS 11: Production of metal powders in wet process (PROC 27b)

9.3.11.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.3.11.2. 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/m³ (MEASE: 1.02.01)	RCR = 0.714
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.789

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.3.12. Worker CS 12: Wet cleaning (PROC 28)

9.3.12.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.3.12.2. Exposure and risks for workers

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

Table 9.40. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	5E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.036
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75
Combined routes, systemic,		RCR = 0.786

Route of exposure and type of effects	Exposure concentration	Risk quantification
long-term		

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 8a was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of dermal 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

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

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

Market sector: Photo-chemicals
Product category formulated: PC 30: Photo-chemicals

Environment contributing scenario(s):		
CS 1	Formulation	ERC 2
Worker contributing scenario(s):		
CS 2	Handling and packaging of liquid substance	PROC 8b
CS 3	Small scale handling and packaging of liquid substance	PROC 9
CS 4	Formulation in fully contained process	PROC 1
CS 5	Formulation in closed continuous process	PROC 2
CS 6	Formulation in closed batch process	PROC 3
CS 7	Formulation in open or semi-closed process	PROC 4
CS 8	Mixing or blending in batch process	PROC 5
CS 9	Wet cleaning	PROC 28

Explanation on the approach taken for the ES

9.4.1. Env CS 1: Formulation (ERC 2)

9.4.1.1. Conditions of use

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

9.4.1.2. Releases

The GES and associated risk assessment are concerned with releases of TCA to waste-water and air occurring during the formulation of TCA at an industrial facility. This waste-water is discharged to freshwater following treatment at a municipal STP. Exposure assessment for the aquatic environment is based on parameter values from the SpERC for formulation of metal compounds[10] ('formulation of metal compounds in other than plastics and paint sectors') and calculation of the maximum tonnage

[10] http://www.arche-consulting.be/content/documents/Eurometaux-2.2a-c.v2.1.pdf

(Msafe) of TCA that can be formulated without risk to the environment. The release factor for waste-water in this SpERC is given as '2% before on-site treatment'. However, all sites formulating TCA will have waste-water treatment plants (WWTPs), predominantly using pH adjustment and precipitation. The Msafe tonnage for formulation is therefore calculated using a release factor (RF) adjusted to include a WWTP efficiency of 99% (i.e. the RF for water is reduced from 2% to 0.02%).

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for formulation of TCA is detailed below.

Table 9.41. The generic exposure scenario (GES) for formulation of TCA

1. Title **ES4: Formulation**	
Life cycle	Formulation - Formulation
Systematic title based on use descriptor	**ERC:** ERC 2 Formulation of preparations containing TCA
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Formulation
Systematic title based on use descriptor (environment)	ERC 2 Formulation of preparations
Processes, tasks, activities covered (environment)	Formulation: delivery, mixing, dissolving and packaging
Environmental Assessment Method	Estimates based on adjusted SpERC RFs are used for calculation of the maximum tonnage that can be safely used without risk to the environment
Product characteristics TCA as solid or aqueous solution. Environmental assessment is based on the modelled emission of TCA in waste-water discharge and TCA emissions to air.	
Amounts used	
Maximum annual safe use at a site (Msafe)	30 tonnes TCA (17.4 tonnes Au metal equivalent)
Frequency and duration of use	
Pattern of release to the environment	300 days per year per site (standard for sector; see ES1)
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default) Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	Not relevant
Other given operational conditions affecting environmental exposure	
None	

Technical conditions and measures at process level (source) to prevent release
Appropriate process control systems shall be implemented.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Waste water: ES 2 Discharge to freshwater via STP: On-site wastewater treatment by chemical precipitation, sedimentation and/or filtration. Efficiency >99 % (chemical precipitation; SpERC for 'Formulation of metal compounds') and off-site municipal sewage treatment plant (STP) Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon) Release factor after on-site treatment: 200 g/T (99% treatment WWTP efficiency applied to 2% RF before on-site treatment) **Air:** Treatment of air emissions by filters, electrostatic precipitation and/or wet scrubbers.(SpERC for 'Formulation of metal compounds') Release factor after on-site treatment: 10 g/T (10% of SpERC RF for air)
Organizational measures to prevent/limit release from site
Regular operator training.
Conditions and measures related to municipal sewage treatment plant (if applicable)

Municipal Sewage Treatment Plant (STP)	Yes
Discharge rate of the Municipal STP	2 000 m^3/d
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)

Conditions and measures related to external treatment of waste for disposal
TCA- and other Au-containing waste is filled into containers and transported to licensed recycling facilities for recovery or disposed of at landfill.
Conditions and measures related to external recovery of waste
TCA- and other Au-containing waste suitable for recycling may be recycled either internally or at licensed recycling facility. The sludge from the on-site treatment plant is processed for metal reclamation (recycling).
3. Exposure and risk estimation

Environment

ERC 2

ES 4 Formulation of TCA

Compartment	**Unit**	**PNEC**	**$PEC_{regional}$**	**C_{local}**	**PEC**	**RCR**	**Methods for calculation of environmental**

							concentrations
Discharge to STP	mg TCA/ L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.1 x 10^{-3} mg/L	1.1 x 10^{-3} mg/L	0.0057	Adjusted SpERC emission factors applied to Msafe tonnage and dilution factor at municipal STP
Freshwater via STP	mg TCA/ L	1.04 $x10^{-3}$ mg/L	2.05 $x10^{-7}$ mg/L	8.70 $x10^{-6}$ mg/L	8.91 $x10^{-6}$ mg/L	0.0086	Adjusted SpERC emission factors applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/ kg w.w.	4.5 mg/kg	4.11 $x10^{-4}$ mg/kg	0.039 mg/kg	0.039 mg/kg	0.087	Adjusted SpERC emission factors applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.
Terrestrial (all scenarios)	mg TCA/ kg w.w.	3.65 mg/kg	1.89 $x10^{-3}$ mg/kg	6.00 $x10^{-7}$ mg/kg	1.89 $x10^{-3}$ mg/kg	0.0005	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)

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

Environment

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

Scaling of the release to air and water environment includes:

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

9.4.1.3. Exposure and risks for man via the environment

Assessment of risks for man via the environment is based on inhalation exposure to airborne particulates containing TCA released to the atmosphere during the formulation of TCA and other TCA compounds.

Table 9.42. Exposure and risks for man via the environment

Annual emission to air (kg TCA)	Emission days per year	Concentration in local air (mg TCA/m^3)	Annual average concentration in air (mg TCA/m^3)	DNEL (mg TCA/m^3)	RCR
0.3	300	2.8 $x10^{-7}$	2.3 $x10^{-7}$	0.007	4.0 $x10^{-5}$

9.4.2. Worker CS 2: Handling and packaging of liquid substance (PROC 8b)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.4.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.4.2.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075

Route of exposure and type of effects	Exposure concentration	Risk quantification
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.4.3. Worker CS 3: Small scale handling and packaging of liquid substance (PROC 9)

Task(s) covered with this contributing scenario: Small scale transfer and filling process.

9.4.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.4.3.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.4.4. Worker CS 4: Formulation in fully contained process (PROC 1)

Task(s) covered with this contributing scenario: Mixing, blending.

9.4.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed process without likelihood of exposure • Pattern of use: Closed system without breaches • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.4.4.2. 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	1E-3 mg/m³ (MEASE: 1.02.01)	RCR < 0.01
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.05

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.4.5. Worker CS 5: Formulation in closed continuous process (PROC 2)

Task(s) covered with this contributing scenario: Mixing, blending.

9.4.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed continuous process with occasional controlled exposure • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.4.5.2. 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	1E-3 mg/m³ (MEASE: 1.02.01)	RCR < 0.01
Inhalation, local, long term	1E-3 mg/m³ (MEASE: 1.02.01)	
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.082

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.4.6. Worker CS 6: Formulation in closed batch process (PROC 3)

Task(s) covered with this contributing scenario: Mixing, blending.

9.4.6.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed batch process with occasional controlled exposure • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes

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.

9.4.6.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.114

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.4.7. Worker CS 7: Formulation in open or semi-closed process (PROC 4)

Task(s) covered with this contributing scenario: Mixing, blending.

9.4.7.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as*

appropriate. • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.4.7.2. Exposure and risks for workers

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

Table 9.48. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.4.8. Worker CS 8: Mixing or blending in batch process (PROC 5)

9.4.8.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*

• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.4.8.2. Exposure and risks for workers

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

Table 9.49. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.4.9. Worker CS 9: Wet cleaning (PROC 28)

9.4.9.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.*

• Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.4.9.2. Exposure and risks for workers

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

Table 9.50. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	5E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.036
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75
Combined routes, systemic, long-term		RCR = 0.786

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 8a was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of dermal 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

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.5. Exposure scenario 5: Use at industrial sites - Production of imaging and printing articles

Market sector: Photo-chemicals
Product category used: PC 30: Photo-chemicals
Sector of use: SU 7: Printing and reproduction of recorded media

Environment contributing scenario(s):		
CS 1	Production of imaging and printing articles	ERC 5
Worker contributing scenario(s):		
CS 2	Handling of the substance	PROC 8b
CS 3	Small scale handling of the substance	PROC 9
CS 4	Fully contained process	PROC 1
CS 5	Closed continuous process	PROC 2
CS 6	Closed batch process	PROC 3
CS 7	Mixing or blending in batch process	PROC 5
CS 8	Wet cleaning	PROC 28

Explanation on the approach taken for the ES

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

9.5.1. Env CS 1: Production of imaging and printing articles (ERC 5)

9.5.1.1. Conditions of use

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

9.5.1.2. Releases

The GES and associated risk assessment are concerned with releases of TCA to waste-water and air occurring during production of imaging and printing articles with TCA at an industrial facility. This waste-water is discharged to freshwater following treatment at a municipal STP. Exposure assessment for the aquatic environment is based on parameter values from the SpERC for 'Industrial use of metals and metal compounds in metallic coating'[11] and calculation of the maximum tonnage (Msafe) of TCA that can be used without risk to environment. Msafe is calculated using release factors (RFs) adjusted to 10% of the values recommend in the SpERC for base metals based on the monetary value of gold (see Section 9.0.2).

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for industrial use of TCA in the production of imaging and printing articles is detailed in the table below.

Table 9.51. The generic exposure scenario (GES) for industrial use of TCA in the production of imaging and printing articles

1. Title **ES5: Use at industrial site - Use in the production of imaging and printing articles**	
Life cycle	Use of TCA in the production of imaging and printing articles
Systematic title based on use descriptor	**ERC:** ERC 5 – Industrial use resulting in inclusion into or onto a matrix
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Use of TCA at industrial site in the production of imaging and printing articles
Systematic title based on use descriptor (environment)	ERC 5 (Industrial use resulting in inclusion into or onto a matrix)
Processes, tasks, activities covered (environment)	Industrial use of TCA for the production of imaging and printing articles: As defined by SpERC for 'Industrial use of metals and metal compounds in metallic coating'[7] - Production of imaging and printing articles - Production of printing plates - Application of imaging and printing chemicals
Environmental Assessment Method	Estimates of environmental emissions based on adjusted SpERC RFs are used for calculation of maximum tonnage that can be used safely without risk to the environment
Product characteristics	

[11] ARCHE (2013) Industrial use of metals and metal compounds in metallic coating. spERC code Eurometaux 5.1 v2.1. Available online at http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/

TCA as aqueous solution. Environmental assessment is based on the release factors detailed in the SpERC for 'Industrial use of metals and metal compounds in metallic coating' and default characteristics for environmental compartments detailed in the ECHA technical guidance and EUSES model.	
Amounts used	
Maximum annual safe use at a site (Msafe)	8 tonnes TCA (4.6 tonnes Au equivalent)
Frequency and duration of use	
Pattern of release to the environment	220 days per year per site (SpERC[7])
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default) Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	Not relevant
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: ES Discharge to freshwater via STP: On-site wastewater treatment by chemical precipitation, sedimentation, electrolysis, reverse osmosis, ion exchange and/or filtration. Efficiency >99% (typical values reported in SpERC for 'Industrial use of metals and metal compounds in metallic coating') and off-site municipal sewage treatment plant (STP) Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon) Release factor after on-site treatment: 500 g/T (10% of SpERC RF for waste-water) **Air:** Treatment of air emissions by cyclones, filters (e.g. fabric, bag, HEPA or ceramic), electrostatic precipitators and/or wet scrubbers. Efficiency 95 to >99% (typical values reported in SpERC for 'Industrial use of metals and metal compounds in metallic coating') Release factor after on-site treatment: 2000 g/T (10% of SpERC RF for air)	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	

Municipal Sewage Treatment Plant (STP)	Yes
Discharge rate of the Municipal STP	2 000 m^3/d (default)
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)

Conditions and measures related to external treatment of waste for disposal

TCA- and other Au-containing waste is filled into containers and transported to licensed recycling facilities for recovery or disposed of at landfill.

Conditions and measures related to external recovery of waste

TCA- and other Au-containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.

3. Exposure and risk estimation

Environment

ERC 5

ES 5 Use at industrial site - Use in the production of imaging and printing articles

Compartment	Unit	PNEC	$PEC_{regional}$	C_{local}	PEC	RCR	Methods for calculation of environmental concentrations
Discharge to STP	mg TCA/L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.03 $x10^{-3}$ mg/L	1.03 $x10^{-3}$ mg/L	0.0051	Adjusted SpERC emission factors applied to Msafe tonnage and dilution factor at municipal STP
Freshwater via STP	mg TCA/L	1.04 $x10^{-3}$ mg/L	2.05 $x10^{-7}$ mg/L	7.91 $x10^{-3}$ mg/L	7.93 $x10^{-3}$ mg/L	0.076	Adjusted SpERC emission factors applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/kg w.w.	4.5 mg/kg	4.11 $x10^{-4}$ mg/kg	0.343 mg/kg	0.344 mg/kg	0.76	Adjusted SpERC emission factors applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.

Terrestrial	mg TCA/kg w.w.	3.65 mg/kg	1.89 $x10^{-3}$ mg/kg	4.4 $x10^{-6}$ mg/kg	1.89 $x10^{-3}$ mg/kg	0.0005	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)

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

Environment

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

Scaling of the release to air and water environment includes:

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

9.5.1.3. Exposure and risks for man via the environment

Assessment of risks for man via the environment is based on inhalation exposure to airborne particulates containing TCA released to the atmosphere during the industrial use of TCA in electroplating or metal surface treatment.

Table 9.52. Exposure and risks for man via the environment

Annual emission to air (kg TCA)	Emission days per year	Concentration in local air (mg TCA/m³)	Annual average concentration in air (mg TCA/m³)	DNEL (mg TCA/m³)	RCR
1.6	220	2.0×10^{-6}	1.2×10^{-6}	0.007	2.9×10^{-4}

9.5.2. Worker CS 2: Handling of the substance (PROC 8b)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.5.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.5.2.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic,		RCR = 0.146

Route of exposure and type of effects	Exposure concentration	Risk quantification
long-term		

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.5.3. Worker CS 3: Small scale handling of the substance (PROC 9)

Task(s) covered with this contributing scenario: Small scale transfer and filling process.

9.5.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.5.3.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071

Route of exposure and type of effects	Exposure concentration	Risk quantification
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.5.4. Worker CS 4: Fully contained process (PROC 1)

9.5.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed process without likelihood of exposure • Pattern of use: Closed system without breaches • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.5.4.2. 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	1E-3 mg/m³ (MEASE: 1.02.01)	RCR < 0.01
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.05

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.5.5. Worker CS 5: Closed continuous process (PROC 2)

9.5.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed continuous process with occasional controlled exposure • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 9.56. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	1E-3 mg/m³ (EMKG Expo tool: 1.02.01)	RCR < 0.01
Inhalation, local, long term	1E-3 mg/m³ (EMKG Expo tool: 1.02.01)	
Dermal, systemic, long term	3E-3 mg/kg bw/day (EMKG Expo tool: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.082

Remarks on exposure data from external estimation tools:

EMKG Expo tool 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.5.6. Worker CS 6: Closed batch process (PROC 3)

9.5.6.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed batch process with occasional controlled exposure • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.5.6.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.114

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.5.7. Worker CS 7: Mixing or blending in batch process (PROC 5)

9.5.7.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*

9.5.7.2. Exposure and risks for workers

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

Table 9.58. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.5.8. Worker CS 8: Wet cleaning (PROC 28)

9.5.8.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.5.8.2. 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	5E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.036
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75
Combined routes, systemic, long-term		RCR = 0.786

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 8a was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of dermal 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

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.6. Exposure scenario 6: Use at industrial sites - Production of printing plates

Market sector: Photo-chemicals
Product category used: PC 30: Photo-chemicals
Sector of use: SU 7: Printing and reproduction of recorded media

Environment contributing scenario(s):		
CS 1	Production of printing plates	ERC 5
Worker contributing scenario(s):		
CS 2	Handling of the substance	PROC 8b
CS 3	Fully contained process	PROC 1
CS 4	Closed continuous process	PROC 2
CS 5	Closed batch process	PROC 3
CS 6	Extrusion	PROC 14
CS 7	Wet cleaning	PROC 28

Explanation on the approach taken for the ES

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

9.6.1. Env CS 1: Production of printing plates (ERC 5)

9.6.1.1. Conditions of use

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

9.6.1.2. Releases

The GES and associated risk assessment are concerned with releases of TCA to waste-water and air occurring during the production of printing plates with TCA at an industrial facility. This waste-water is discharged to freshwater following treatment at a municipal STP. Exposure assessment for the aquatic environment is based on parameter values from the SpERC for 'Industrial use of metals and metal compounds in metallic coating'[12] and calculation of the maximum tonnage (Msafe) of TCA that can be used without risk to environment. Msafe is calculated using release factors (RFs) adjusted to 10% of the values recommend in the SpERC for base metals based on the monetary value of gold (see Section 9.0.2).

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for industrial use of TCA in the production of printing plates is detailed below.

Table 9.60. The generic exposure scenario (GES) for industrial use of TCA in the production of printing plates

1. Title **ES6: Use at industrial site - Use in the production of printing plates**	
Life cycle	Use of TCA in the production of printing plates
Systematic title based on use descriptor	**ERC:** ERC 5 – Industrial use resulting in inclusion into or onto a matrix
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Use of TCA at industrial site in the production of printing plates
Systematic title based on use descriptor (environment)	ERC 5 (Industrial use resulting in inclusion into or onto a matrix)
Processes, tasks, activities covered (environment)	Industrial use of TCA in the production of printing plates: As defined by SpERC for 'Industrial use of metals and metal compounds in metallic coating'[7] - Production of imaging and printing articles - Production of printing plates - Application of imaging and printing chemicals
Environmental Assessment Method	Estimates of environmental emissions based on adjusted SpERC RFs are used for calculation of maximum tonnage that can be used safely without risk to the environment
Product characteristics TCA as aqueous solution. Environmental assessment is based on the release factors detailed in the SpERC for 'Industrial use of metals and metal compounds in metallic coating' and default characteristics for environmental compartments detailed in the ECHA technical guidance and EUSES model.	
Amounts used	
Maximum annual safe use at a site (Msafe)	8 tonnes TCA (4.6 tonnes Au equivalent)
Frequency and duration of use	

[12] ARCHE (2013) Industrial use of metals and metal compounds in metallic coating. spERC code Eurometaux 5.1 v2.1. Available online at http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/

Pattern of release to the environment	220 days per year per site (SpERC[7])
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default) Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	Not relevant
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: ES Discharge to freshwater via STP: On-site wastewater treatment by chemical precipitation, sedimentation, electrolysis, reverse osmosis, ion exchange and/or filtration. Efficiency >99% (typical values reported in SpERC for 'Industrial use of metals and metal compounds in metallic coating') and off-site municipal sewage treatment plant (STP) Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon) Release factor after on-site treatment: 500 g/T (10% of SpERC RF for waste-water) **Air:** Treatment of air emissions by cyclones, filters (e.g. fabric, bag, HEPA or ceramic), electrostatic precipitators and/or wet scrubbers. Efficiency 95 to >99% (typical values reported in SpERC for 'Industrial use of metals and metal compounds in metallic coating') Release factor after on-site treatment: 2000 g/T (10% of SpERC RF for air)	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	
Municipal Sewage Treatment Plant (STP)	Yes
Discharge rate of the Municipal STP	2 000 m^3/d (default)
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)
Conditions and measures related to external treatment of waste for disposal	
TCA- and other Au-containing waste is filled into containers and transported to licensed recycling facilities for recovery or disposed of at landfill.	

Conditions and measures related to external recovery of waste

TCA- and other Au-containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.

3. Exposure and risk estimation

Environment

ERC 5

ES 6 Use at industrial site - Use in the production of printing plates

Compartment	**Unit**	**PNEC**	**$PEC_{regional}$**	**C_{local}**	**PEC**	**RCR**	**Methods for calculation of environmental concentrations**
Discharge to STP	mg TCA/L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.03 $x10^{-3}$ mg/L	1.03 $x10^{-3}$ mg/L	0.0051	Adjusted SpERC emission factors applied to Msafe tonnage and dilution factor at municipal STP
Freshwater via STP	mg TCA/L	1.04 $x10^{-3}$ mg/L	2.05 $x10^{-7}$ mg/L	7.91 $x10^{-3}$ mg/L	7.93 $x10^{-3}$ mg/L	0.076	Adjusted SpERC emission factors applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/kg w.w.	4.5 mg/kg	4.11 $x10^{-4}$ mg/kg	0.343 mg/kg	0.344 mg/kg	0.76	Adjusted SpERC emission factors applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.
Terrestrial	mg TCA/kg w.w.	3.65 mg/kg	1.89 $x10^{-3}$ mg/kg	4.4 $x10^{-6}$ mg/kg	1.89 $x10^{-3}$ mg/kg	0.0005	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)

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

Environment

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

toolbox/du-scaling-tool)

Scaling of the release to air and water environment includes:

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

9.6.1.3. Exposure and risks for man via the environment

Assessment of risks for man via the environment is based on inhalation exposure to airborne particulates containing TCA released to the atmosphere during the industrial use of TCA in electroplating or metal surface treatment.

Table 9.61. Exposure and risks for man via the environment

Annual emission to air (kg TCA)	Emission days per year	Concentration in local air (mg TCA/m^3)	Annual average concentration in air (mg TCA/m^3)	DNEL (mg TCA/m^3)	RCR
1.6	220	2.0 x10^{-6}	1.2 x10^{-6}	0.007	2.9 x10^{-4}

9.6.2. Worker CS 2: Handling of the substance (PROC 8b)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.6.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.6.2.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

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

9.6.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed process without likelihood of exposure • Pattern of use: Closed system without breaches • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.6.3.2. 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	1E-3 mg/m³ (MEASE: 1.02.01)	RCR < 0.01
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.05

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.6.4. Worker CS 4: Closed continuous process (PROC 2)

9.6.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed continuous process with occasional controlled exposure • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.6.4.2. 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	1E-3 mg/m³ (EMKG Expo tool: 1.02.01)	RCR < 0.01
Inhalation, local, long term	1E-3 mg/m³ (EMKG Expo tool: 1.02.01)	
Dermal, systemic, long term	3E-3 mg/kg bw/day (EMKG Expo tool: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.082

Remarks on exposure data from external estimation tools:

EMKG Expo tool 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.6.5. Worker CS 5: Closed batch process (PROC 3)

9.6.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Closed batch process with occasional controlled exposure • Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.* • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.

9.6.5.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	1.7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.043
Combined routes, systemic, long-term		RCR = 0.114

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.6.6. Worker CS 6: Extrusion (PROC 14)

9.6.6.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.

9.6.6.2. Exposure and risks for workers

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

Table 9.66. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.6.7. Worker CS 7: Wet cleaning (PROC 28)

9.6.7.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.

9.6.7.2. Exposure and risks for workers

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

Table 9.67. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	5E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.036
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75
Combined routes, systemic, long-term		RCR = 0.786

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 8a was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of dermal 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

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.7. Exposure scenario 7: Use at industrial sites - Application of imaging and printing chemicals

Market sector: Photo-chemicals
Product category used: PC 30: Photo-chemicals
Sector of use: SU 7: Printing and reproduction of recorded media

Environment contributing scenario(s):		
CS 1	Application of imaging and printing chemicals	ERC 5
Worker contributing scenario(s):		
CS 2	Handling of the substance	PROC 8b
CS 3	Mixing or blending in batch process	PROC 5
CS 4	Dipping and pouring	PROC 13
CS 5	Wet cleaning	PROC 28

Explanation on the approach taken for the ES

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

9.7.1. Env CS 1: Application of imaging and printing chemicals (ERC 5)

9.7.1.1. Conditions of use

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

9.7.1.2. Releases

The GES and associated risk assessment are concerned with releases of TCA to waste-water and air occurring during the application of imaging and printing chemicals with TCA at an industrial facility. This waste-water is discharged to freshwater following treatment at a municipal STP. Exposure assessment for the aquatic environment is based on parameter values from the SpERC for 'Industrial use of metals and metal compounds in metallic coating'[13] and calculation of the maximum tonnage (Msafe) of TCA that can be used without risk to environment. Msafe is calculated using release factors (RFs) adjusted to 10% of the values recommend in the SpERC for base metals based on the monetary value of gold (see Section 9.0.2).

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for industrial use of TCA in the application of imaging and printing chemicals is detailed below.

Table 9.68. The generic exposure scenario (GES) for industrial use of TCA in the application of imaging and printing chemicals

1. Title **ES7: Use at industrial site - Use in the application of imaging and printing chemicals**	
Life cycle	Use of TCA in the application of imaging and printing chemicals
Systematic title based on use descriptor	**ERC:** ERC 5 – Industrial use resulting in inclusion into or onto a matrix
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Use of TCA at industrial site in the application of imaging and printing chemicals
Systematic title based on use descriptor (environment)	ERC 5 (Industrial use resulting in inclusion into or onto a matrix)
Processes, tasks, activities covered (environment)	Industrial use of TCA the application of imaging and printing chemicals: As defined by SpERC for 'Industrial use of metals and metal compounds in metallic coating'[7] - Production of imaging and printing articles - Production of printing plates - Application of imaging and printing chemicals
Environmental Assessment Method	Estimates of environmental emissions based on adjusted SpERC RFs are used for calculation of maximum tonnage that can be used safely without risk to the environment
Product characteristics TCA as aqueous solution. Environmental assessment is based on the release factors detailed in the SpERC for 'Industrial use of metals and metal compounds in metallic coating' and default characteristics for environmental compartments detailed in the ECHA technical guidance and EUSES model.	
Amounts used	

[13] ARCHE (2013) Industrial use of metals and metal compounds in metallic coating. spERC code Eurometaux 5.1 v2.1. Available online at http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/

Maximum annual safe use at a site (Msafe)	8 tonnes TCA (4.6 tonnes Au equivalent)
Frequency and duration of use	
Pattern of release to the environment	220 days per year per site (SpERC[7])
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default) Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	Not relevant
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: ES Discharge to freshwater via STP: On-site wastewater treatment by chemical precipitation, sedimentation, electrolysis, reverse osmosis, ion exchange and/or filtration. Efficiency >99% (typical values reported in SpERC for 'Industrial use of metals and metal compounds in metallic coating') and off-site municipal sewage treatment plant (STP) Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon) Release factor after on-site treatment: 500 g/T (10% of SpERC RF for waste-water) **Air:** Treatment of air emissions by cyclones, filters (e.g. fabric, bag, HEPA or ceramic), electrostatic precipitators and/or wet scrubbers. Efficiency 95 to >99% (typical values reported in SpERC for 'Industrial use of metals and metal compounds in metallic coating') Release factor after on-site treatment: 2000 g/T (10% of SpERC RF for air)	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	
Municipal Sewage Treatment Plant (STP)	Yes
Discharge rate of the Municipal STP	2 000 m^3/d (default)
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)

Conditions and measures related to external treatment of waste for disposal

TCA- and other Au-containing waste is filled into containers and transported to licensed recycling facilities for recovery or disposed of at landfill.

Conditions and measures related to external recovery of waste

TCA- and other Au-containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.

3. Exposure and risk estimation

Environment

ERC 5

ES 7 Use at industrial site - Use in the application of imaging and printing chemicals

Compartment	**Unit**	**PNEC**	**$PEC_{regional}$**	**C_{local}**	**PEC**	**RCR**	**Methods for calculation of environmental concentrations**
Discharge to STP	mg TCA/L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.03 $x10^{-3}$ mg/L	1.03 $x10^{-3}$ mg/L	0.0051	Adjusted SpERC emission factors applied to Msafe tonnage and dilution factor at municipal STP
Freshwater via STP	mg TCA/L	1.04 $x10^{-3}$ mg/L	2.05 $x10^{-7}$ mg/L	7.91 $x10^{-3}$ mg/L	7.93 $x10^{-3}$ mg/L	0.076	Adjusted SpERC emission factors applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/kg w.w.	4.5 mg/kg	4.11 $x10^{-4}$ mg/kg	0.343 mg/kg	0.344 mg/kg	0.76	Adjusted SpERC emission factors applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.

Terrestrial	mg TCA/kg w.w.	3.65 mg/kg	1.89 $x10^{-3}$ mg/kg	4.4 $x10^{-6}$ mg/kg	1.89 $x10^{-3}$ mg/kg	0.0005	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)

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

Environment

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

Scaling of the release to air and water environment includes:

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

9.7.1.3. Exposure and risks for man via the environment

Assessment of risks for man via the environment is based on inhalation exposure to airborne particulates containing TCA released to the atmosphere during the industrial use of TCA in electroplating or metal surface treatment.

Table 9.69. Exposure and risks for man via the environment

Annual emission to air (kg TCA)	Emission days per year	Concentration in local air (mg TCA/m³)	Annual average concentration in air (mg TCA/m³)	DNEL (mg TCA/m³)	RCR
1.6	220	2.0×10^{-6}	1.2×10^{-6}	0.007	2.9×10^{-4}

9.7.2. Worker CS 2: Handling of the substance (PROC 8b)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.7.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.7.2.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic,		RCR = 0.146

Route of exposure and type of effects	Exposure concentration	Risk quantification
long-term		

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.7.3. Worker CS 3: Mixing or blending in batch process (PROC 5)

9.7.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*

9.7.3.2. 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	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075

Route of exposure and type of effects	Exposure concentration	Risk quantification
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.7.4. Worker CS 4: Dipping and pouring (PROC 13)

9.7.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.7.4.2. 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	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071

Route of exposure and type of effects	Exposure concentration	Risk quantification
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.7.5. Worker CS 5: Wet cleaning (PROC 28)

9.7.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.7.5.2. Exposure and risks for workers

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

Table 9.73. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	5E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.036
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75
Combined routes, systemic, long-term		RCR = 0.786

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 8a was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of dermal 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

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.8. Exposure scenario 8: Widespread use by professional workers - Use in photographic applications

Market sector: Photo-chemicals
Product category used: PC 30: Photo-chemicals
Sector of use: SU 7: Printing and reproduction of recorded media

Environment contributing scenario(s):		
CS 1	Use in photographic applications	ERC 8c
Worker contributing scenario(s):		
CS 2	Handling of preparations at non-dedicated facilities	PROC 8a
CS 3	Handling of preparations at dedicated facilities	PROC 8b
CS 4	Small scale handling of preparations	PROC 9
CS 5	Open or semi-closed process	PROC 4
CS 6	Mixing or blending in batch process	PROC 5
CS 7	Application of the substance by rolling or brushing	PROC 10

Explanation on the approach taken for the ES

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

9.8.1. Env CS 1: Use in photographic applications (ERC 8c)

9.8.1.1. Conditions of use

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

9.8.1.2. Releases

The GES and associated risk assessment are concerned with releases of TCA to waste-water and air during the use by professional workers of TCA in photographic applications. This waste-water is assumed to be treated at a municipal STP before discharge to freshwater. Exposure assessment for the aquatic environment is based on calculation of the maximum safe tonnage (Msafe) of TCA that can

be used for photographic applications by professional workers; modelling of environmental exposure is based on adjustment to release factors (RFs) defined by ERC 8c.

Table 9.74. the generic exposure scenario (GES) for use of TCA in photographic applications

1. Title **ES8: Use by professional workers - Use in electroplating or metal surface treatment**	
Life cycle	Professional use of TCA in photographic applications
Systematic title based on use descriptor	**ERC:** ERC 8c
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Use by professional in photographic applications
Systematic title based on use descriptor (environment)	ERC 8c (Widespread use leading to inclusion into/onto article (indoor))
Processes, tasks, activities covered (environment)	Professional use of TCA in photographic applications. As defined by ERC 8c release scenario adjusted for monetary value of gold
Environmental Assessment Method	Estimates based on ERC 8c for 'Widespread use leading to inclusion into/onto article (indoor)' adjusted for monetary value of gold are used for calculation of maximum tonnage that can be used safely without risk to the environment.
Product characteristics TCA as aqueous solution. Environmental assessment is based on adjustment to ERC 8c release factors and default characteristics for environmental compartments detailed in the ECHA technical guidance and EUSES model.	
Amounts used	
Maximum annual safe use at a site (Msafe)	130 kg TCA (75 kg Au equivalent)
Frequency and duration of use	
Pattern of release to the environment	220 days per year per site (surface treatment SpERC for industrial setting; this assumes an average working year)
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default) Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	NR
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and	

releases to soil

Waste water:

ES Discharge to freshwater via STP:

Release to domestic waste-water

and off-site municipal sewage treatment plant (STP)

Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon)

Release factor after on-site treatment: 130,000 g/T (ERC 8c RF adjusted to 10% for monetary value of Au as detailed in section 9.02)

Air:

Release factor after on-site treatment: 15,000 g/T (ERC 8c RF adjusted to 10% based on monetary value of Au as detailed in section 9.02)

Organizational measures to prevent/limit release from site

Safety data sheet and instructions for professional use

Conditions and measures related to municipal sewage treatment plant (if applicable)

Municipal Sewage Treatment Plant (STP)	Yes
Discharge rate of the Municipal STP	2 000 m^3/d (default)
Fate of the sludge of the Municipal STP	Worst case scenario assumed that sludge is applied to land

Conditions and measures related to external treatment of waste for disposal

Not relevant for professional use

Conditions and measures related to external recovery of waste

Not relevant for professional use

3. Exposure and risk estimation

Environment

ERC 8c

ES 8 Use by professional worker - Use in photographic applications

Compartment	**Unit**	**PNEC**	**$PEC_{regional}$**	**C_{local}**	**PEC**	**RCR**	**Methods for calculation of environmental concentrations**
ES Discharge to STP	mg TCA/L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.0 $x10^{-3}$ mg/L	1.0 $x10^{-3}$ mg/L	0.0050	10% RF for ERC 8c applied to Msafe tonnage and dilution factor at municipal STP

ES Freshwater via STP	mg TCA/L	1.04 $x10^{-3}$ mg/L	2.05 $x10^{-7}$ mg/L	7.73 $x10^{-5}$ mg/L	7.75 $x10^{-5}$ mg/L	0.075	10% RF for ERC 8c applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/ kg w.w.	4.5 mg/kg	4.11 $x10^{-4}$ mg/kg	0.332 mg/kg	0.333 mg/kg	0.74	10% RF for ERC 8c applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.
Terrestrial	mg TCA/ kg w.w.	3.65 mg/kg	1.89 $x10^{-3}$ mg/kg	5.32 $x10^{-6}$ mg/kg	1.89 $x10^{-3}$ mg/kg	0.0095	Modelled increase in soil concentrations due to deposition from atmospheric emissions and application of sewage sludge to land

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

Environment

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

Scaling of the release to air and water environment includes:

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

9.8.1.3. Exposure and risks for man via the environment

Not relevant. TCA is used as an aqueous solution in small quantities. Emissions to air are therefore considered to be negligible.

9.8.2. Worker CS 2: Handling of preparations at non-dedicated facilities (PROC 8a)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.8.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 15 - 60 min [Effectiveness Inhalation: 80%, Dermal: 80%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.8.2.2. Exposure and risks for workers

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

Table 9.75. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.175
Combined routes, systemic, long-term		RCR = 0.246

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.8.3. Worker CS 3: Handling of preparations at dedicated facilities (PROC 8b)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.8.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 15 - 60 min [Effectiveness Inhalation: 80%, Dermal: 80%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.8.3.2. Exposure and risks for workers

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

Table 9.76. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.175
Combined routes, systemic, long-term		RCR = 0.246

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.8.4. Worker CS 4: Small scale handling of preparations (PROC 9)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.8.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 15 - 60 min [Effectiveness Inhalation: 80%, Dermal: 80%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.8.4.2. Exposure and risks for workers

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

Table 9.77. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.175
Combined routes, systemic, long-term		RCR = 0.246

Remarks on exposure data from external estimation tools:

MEASE 1.02.01

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

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

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

Task(s) covered with this contributing scenario: Mixing and blending.

9.8.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 60 - 240 min [Effectiveness Inhalation: 40%, Dermal: 40%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.8.5.2. Exposure and risks for workers

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

Table 9.78. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.06 mg/m³ (MEASE: 1.02.01)	RCR = 0.429
Dermal, systemic, long term	2E-4 mg/kg bw/day (MEASE: 1.02.01)	RCR < 0.01
Combined routes, systemic,		RCR = 0.434

Route of exposure and type of effects	Exposure concentration	Risk quantification
long-term		

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

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

9.8.6.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 60 - 240 min [Effectiveness Inhalation: 40%, Dermal: 40%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.8.6.2. Exposure and risks for workers

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

Table 9.79. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.06 mg/m³ (MEASE: 1.02.01)	RCR = 0.429
Dermal, systemic, long term	5E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.125
Combined routes, systemic, long-term		RCR = 0.554

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.8.7. Worker CS 7: Application of the substance by rolling or brushing (PROC 10)

9.8.7.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 15 - 60 min [Effectiveness Inhalation: 80%, Dermal: 80%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.8.7.2. Exposure and risks for workers

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

Table 9.80. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.175
Combined routes, systemic, long-term		RCR = 0.246

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.9. Exposure scenario 9: Use at industrial sites - Use in electrochemical and galvanic plating

Market sector: Electrochemical and galvanic plating
Product category used: PC 14: Metal surface treatment products, including galvanic and electroplating products
Sector of use: SU 14: Manufacture of basic metals, including alloys; SU 15: Manufacture of fabricated metal products, except machinery and equipment

Environment contributing scenario(s):		
CS 1	Use in electrochemical and galvanic plating	ERC 5
Worker contributing scenario(s):		
CS 2	Small scale handling of the substance	PROC 9
CS 3	Open or semi-closed process	PROC 4
CS 4	Dipping and pouring	PROC 13
CS 5	Wet cleaning	PROC 28

Explanation on the approach taken for the ES

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

9.9.1. Env CS 1: Use in electrochemical and galvanic plating (ERC 5)

9.9.1.1. Conditions of use

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

9.9.1.2. Releases

The GES and associated risk assessment are concerned with releases of TCA to waste-water and air occurring during surface treatment or plating with TCA at an industrial facility. This waste-water is

discharged to freshwater following treatment at a municipal STP. Exposure assessment for the aquatic environment is based on parameter values from the SpERC for 'Industrial use of metals and metal compounds in metallic coating'[14] and calculation of the maximum tonnage (Msafe) of TCA that can be used without risk to environment. Msafe is calculated using release factors (RFs) adjusted to 10% of the values recommend in the SpERC for base metals based on the monetary value of gold (see Section 9.0.2).

A summary of the emission characteristics used to quantify the environmental aspects of the generic exposure scenario (GES) for industrial use of TCA in electroplating or surface treatment is detailed below.

Table 9.81. The generic exposure scenario (GES) for industrial use of TCA in electroplating or surface treatment

1. Title **ES9: Use at industrial site - Use in electroplating or metal surface treatment**	
Life cycle	Use of TCA in electroplating or metal surface treatment
Systematic title based on use descriptor	**ERC:** ERC 5 – Industrial use resulting in inclusion into or onto a matrix
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Use of TCA at industrial site in electroplating or metal surface treatment
Systematic title based on use descriptor (environment)	ERC 5 (Industrial use resulting in inclusion into or onto a matrix)
Processes, tasks, activities covered (environment)	Industrial use of TCA for electroplating or metal surface treatment: As defined by SpERC for 'Industrial use of metals and metal compounds in metallic coating'[7] - Production of imaging and printing articles - Production of printing plates - Application of imaging and printing chemicals
Environmental Assessment Method	Estimates of environmental emissions based on adjusted SpERC RFs are used for calculation of maximum tonnage that can be used safely without risk to the environment
Product characteristics TCA as aqueous solution. Environmental assessment is based on the release factors detailed in the SpERC for 'Industrial use of metals and metal compounds in metallic coating' and default characteristics for environmental compartments detailed in the ECHA technical guidance and EUSES model.	
Amounts used	
Maximum annual safe use at a site (Msafe)	8 tonnes TCA (4.6 tonnes Au equivalent)
Frequency and duration of use	

[14] ARCHE (2013) Industrial use of metals and metal compounds in metallic coating. spERC code Eurometaux 5.1 v2.1. Available online at http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/

Pattern of release to the environment	220 days per year per site (SpERC[7])
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default) Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	Not relevant
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
Appropriate process control systems shall be implemented.	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: ES Discharge to freshwater via STP: On-site wastewater treatment by chemical precipitation, sedimentation, electrolysis, reverse osmosis, ion exchange and/or filtration. Efficiency >99% (typical values reported in SpERC for 'Industrial use of metals and metal compounds in metallic coating') and off-site municipal sewage treatment plant (STP) Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon) Release factor after on-site treatment: 500 g/T (10% of SpERC RF for waste-water) **Air:** Treatment of air emissions by cyclones, filters (e.g. fabric, bag, HEPA or ceramic), electrostatic precipitators and/or wet scrubbers. Efficiency 95 to >99% (typical values reported in SpERC for 'Industrial use of metals and metal compounds in metallic coating') Release factor after on-site treatment: 2000 g/T (10% of SpERC RF for air)	
Organizational measures to prevent/limit release from site	
Regular operator training.	
Conditions and measures related to municipal sewage treatment plant (if applicable)	
Municipal Sewage Treatment Plant (STP)	Yes
Discharge rate of the Municipal STP	2 000 m^3/d (default)
Fate of the sludge from Municipal STP	The sludge is incinerated (with ash going to landfill)
Conditions and measures related to external treatment of waste for disposal	
TCA- and other Au-containing waste is filled into containers and transported to licensed recycling facilities for recovery or disposed of at landfill.	

Conditions and measures related to external recovery of waste

TCA- and other Au-containing waste suitable for recycling may be recycled either internally or at licensed recycling facility.

3. Exposure and risk estimation

Environment

ERC 5

ES 9 Use at industrial site - Use in electroplating or metal surface

Compartment	Unit	PNEC	$PEC_{regional}$	C_{local}	PEC	RCR	Methods for calculation of environmental concentrations
Discharge to STP	mg TCA/L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.03 $x10^{-3}$ mg/L	1.03 $x10^{-3}$ mg/L	0.0051	Adjusted SpERC emission factors applied to Msafe tonnage and dilution factor at municipal STP
Freshwater via STP	mg TCA/L	1.04 $x10^{-3}$ mg/L	2.05 $x10^{-7}$ mg/L	7.91 $x10^{-3}$ mg/L	7.93 $x10^{-3}$ mg/L	0.076	Adjusted SpERC emission factors applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/kg w.w.	4.5 mg/kg	4.11 $x10^{-4}$ mg/kg	0.343 mg/kg	0.344 mg/kg	0.76	Adjusted SpERC emission factors applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.
Terrestrial	mg TCA/kg w.w.	3.65 mg/kg	1.89 $x10^{-3}$ mg/kg	4.4 $x10^{-6}$ mg/kg	1.89 $x10^{-3}$ mg/kg	0.0005	Modelled increase in soil concentrations due to deposition from atmospheric emissions (i.e. assuming no application of sewage sludge to land)

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

Environment

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

Scaling of the release to air and water environment includes:

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

9.9.1.3. Exposure and risks for man via the environment

Assessment of risks for man via the environment is based on inhalation exposure to airborne particulates containing TCA released to the atmosphere during the industrial use of TCA in electroplating or metal surface treatment.

Table 9.82. Exposure and risks for man via the environment

Annual emission to air (kg TCA)	Emission days per year	Concentration in local air (mg TCA/m³)	Annual average concentration in air (mg TCA/m³)	DNEL (mg TCA/m³)	RCR
1.6	220	2.0×10^{-6}	1.2×10^{-6}	0.007	2.9×10^{-4}

9.9.2. Worker CS 2: Small scale handling of the substance (PROC 9)

Task(s) covered with this contributing scenario: Small scale transfer and filling process.

9.9.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.9.2.2. Exposure and risks for workers

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

Table 9.83. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic,		RCR = 0.146

Route of exposure and type of effects	Exposure concentration	Risk quantification
long-term		

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

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

Task(s) covered with this contributing scenario: Mixing and blending.

9.9.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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 *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.* • Gloves as precautionary measure: Gloves protecting from local effects to the skin (high hazard) *Due to the potential adverse effects of the substance to skin, protective gloves according to EN 374 have to be worn at all workplaces. Additionally, face protection is required to be worn as appropriate.*

9.9.3.2. Exposure and risks for workers

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

Table 9.84. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.05 mg/m³ (MEASE: 1.02.01)	RCR = 0.357

Route of exposure and type of effects	Exposure concentration	Risk quantification
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.432

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.9.4. Worker CS 4: Dipping and pouring (PROC 13)

9.9.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.9.4.2. Exposure and risks for workers

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

Table 9.85. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	3E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.075
Combined routes, systemic, long-term		RCR = 0.146

Remarks on exposure data from external estimation tools:

MEASE 1.02.01

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.9.5. Worker CS 5: Wet cleaning (PROC 28)

9.9.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 0%, Dermal: 0%]
Technical and organisational conditions and measures
• Pattern of use: Non-dispersive use • Pattern of exposure control: Direct handling • Contact level: Extensive • Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer’s information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.9.5.2. Exposure and risks for workers

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

Table 9.86. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	5E-3 mg/m³ (MEASE: 1.02.01)	RCR = 0.036
Dermal, systemic, long term	0.03 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.75
Combined routes, systemic, long-term		RCR = 0.786

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: According to ECHA Guidance R. 12 (Version 3.0, December 2015) PROC 28 should be used as descriptor for cleaning and maintenance activities. In MEASE, Version 1.02.01, PROC 28 is not available and PROC 8a was used as surrogate in MEASE for the exposure calculation.
Dermal, systemic, long term
For calculation of dermal 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

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.10. Exposure scenario 10: Widespread use by professional workers - Use in electrochemical and galvanic plating

Market sector: Electrochemical and galvanic plating
Product category used: PC 14: Metal surface treatment products, including galvanic and electroplating products
Sector of use: SU 14: Manufacture of basic metals, including alloys; SU 15: Manufacture of fabricated metal products, except machinery and equipment

Environment contributing scenario(s):		
CS 1	Use in electrochemical and galvanic plating	ERC 8c
Worker contributing scenario(s):		
CS 2	Handling of preparations at non-dedicated facilities	PROC 8a
CS 3	Small scale handling of preparations	PROC 9
CS 4	Open or semi-closed process	PROC 4
CS 5	Dipping and pouring	PROC 13

Explanation on the approach taken for the ES

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

9.10.1. Env CS 1: Use in electrochemical and galvanic plating (ERC 8c)

9.10.1.1. Conditions of use

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

9.10.1.2. Releases

The GES and associated risk assessment are concerned with the releases of TCA to waste-water during use by professional workers in electroplating or metal surface treatment. This waste-water is

assumed to be treated at a municipal STP before discharge to freshwater. Exposure assessment for the aquatic environment is based on calculation of the maximum safe tonnage (Msafe) of TCA that can be used for electroplating or metal surface treatment by professional workers; modelling of environmental exposure is based on adjustment to release factors (RFs) defined by ERC 8c.

Table 9.86. The generic exposure scenario (GES) for professional use of TCA in electroplating or metal surface treatment

1. Title **ES10: Use by professional workers - Use in electroplating or metal surface treatment**	
Life cycle	Professional use of TCA in electroplating or metal surface treatment
Systematic title based on use descriptor	**ERC:** ERC 8c
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure	
Environmental related free short title	Use by professional in electroplating or metal surface treatment
Systematic title based on use descriptor (environment)	ERC 8c (Widespread use leading to inclusion into/onto article (indoor))
Processes, tasks, activities covered (environment)	Professional use of TCA for electroplating or metal surface treatment: As defined by ERC 8c release scenario adjusted for monetary value of gold
Environmental Assessment Method	Estimates based on ERC 8c for 'Widespread use leading to inclusion into/onto article (indoor)' adjusted for monetary value of gold are used for calculation of maximum tonnage that can be used safely without risk to the environment.
Product characteristics TCA as aqueous solution. Environmental assessment is based on adjustment to ERC 8c release factors and default characteristics for environmental compartments detailed in the ECHA technical guidance and EUSES model.	
Amounts used	
Maximum annual safe use at a site (Msafe)	130 kg TCA (75 kg Au equivalent)
Frequency and duration of use	
Pattern of release to the environment	220 days per year per site (surface treatment SpERC for industrial setting; this assumes an average working year)
Environment factors not influenced by risk management	
Receiving surface water flow rate	STP: 2,000 m^3/d (default) Receiving water: 18,000 m^3/d (default)
Dilution capacity, freshwater	Discharge to freshwater via STP: DF = 10 (default)
Dilution capacity, marine	Not relevant
Other given operational conditions affecting environmental exposure	

None
Technical conditions and measures at process level (source) to prevent release
Appropriate process control systems shall be implemented.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Waste water: ES Discharge to freshwater via STP: Release to domestic waste-water and off-site municipal sewage treatment plant (STP) Efficiency 88.7% (based on standard TGD parameters & measured partition coefficient for TCA in relation to SPM normalised to organic carbon) Release factor after on-site treatment: 130,000 g/T (i.e. ERC 8c RF adjusted to 10% for monetary value of Au as detailed in section 9.02) **Air:** Release factor after on-site treatment: 15,000 g/T (ERC 8c RF adjusted to 10% based on monetary value of Au as detailed in section 9.02)
Organizational measures to prevent/limit release from site
Safety data sheet and instructions for professional use
Conditions and measures related to municipal sewage treatment plant (if applicable)

Municipal Sewage Treatment Plant (STP)	Yes
Discharge rate of the Municipal STP	2 000 m^3/d (default)
Fate of the sludge from Municipal STP	Worst case scenario assumed that sludge is applied to land

Conditions and measures related to external treatment of waste for disposal
Not relevant for professional use
Conditions and measures related to external recovery of waste
Not relevant for professional use
3. Exposure and risk estimation

Environment

ERC 8c

ES 10 Use by professional worker - Use in electroplating or metal surface treatment

Compartment	Unit	PNEC	$PEC_{regional}$	C_{local}	PEC	RCR	Methods for calculation of environmental concentrations
ES Discharge to STP	mg TCA/L	0.2 mg/L	2.05 $x10^{-7}$ mg/L	1.0 $x10^{-3}$ mg/L	1.0 $x10^{-3}$ mg/L	0.0050	10% RF for ERC 8c applied to Msafe tonnage and dilution factor at municipal STP

ES Freshwater via STP	mg TCA/ L	1.04 $x10^{-3}$ mg/L	2.05 $x10^{-7}$ mg/L	7.73 $x10^{-5}$ mg/L	7.75 $x10^{-5}$ mg/L	0.075	10% RF for ERC 8c applied to Msafe tonnage and value for STP removal efficiency measured on measured partition coefficient. Plus dilution in ultimate receiving water body based on TGD default
Freshwater sediment via STP	mg TCA/ kg w.w.	4.5 mg/kg	4.11 $x10^{-4}$ mg/kg	0.332 mg/kg	0.333 mg/kg	0.74	10% RF for ERC 8c applied to Msafe tonnage. Partitioning to SPM/sediment based on measured partition coefficient.
Terrestrial	mg TCA/ kg w.w.	3.65 mg/kg	1.89 $x10^{-3}$ mg/kg	5.32 $x10^{-6}$ mg/kg	1.89 $x10^{-3}$ mg/kg	0.0095	Modelled increase in soil concentrations due to deposition from atmospheric emissions and application of sewage sludge to land

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

Environment

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

Scaling of the release to air and water environment includes:

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

9.10.1.3. Exposure and risks for man via the environment

Not relevant. TCA is used as an aqueous solution in small quantities. Emissions to air are therefore considered to be negligible.

9.10.2. Worker CS 2: Handling of preparations at non-dedicated facilities (PROC 8a)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.10.2.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 15 - 60 min [Effectiveness Inhalation: 80%, Dermal: 80%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.10.2.2. Exposure and risks for workers

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

Table 9.87. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.175
Combined routes, systemic, long-term		RCR = 0.246

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.10.3. Worker CS 3: Small scale handling of preparations (PROC 9)

Task(s) covered with this contributing scenario: Transfer and filling process.

9.10.3.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 15 - 60 min [Effectiveness Inhalation: 80%, Dermal: 80%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.10.3.2. Exposure and risks for workers

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

Table 9.88. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	7E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.175
Combined routes, systemic, long-term		RCR = 0.246

Remarks on exposure data from external estimation tools:

MEASE 1.02.01

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

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.10.4. Worker CS 4: Open or semi-closed process (PROC 4)

Task(s) covered with this contributing scenario: Mixing and blending.

9.10.4.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 60 - 240 min [Effectiveness Inhalation: 40%, Dermal: 40%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Non-direct handling
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.10.4.2. Exposure and risks for workers

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

Table 9.89. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.06 mg/m³ (MEASE: 1.02.01)	RCR = 0.429
Dermal, systemic, long term	2E-4 mg/kg bw/day (MEASE: 1.02.01)	RCR < 0.01
Combined routes, systemic,		RCR = 0.434

Route of exposure and type of effects	Exposure concentration	Risk quantification
long-term		

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.10.5. Worker CS 5: Dipping and pouring (PROC 13)

9.10.5.1. Conditions of use

Product (Article) characteristics
• Physical form of substance: Liquid • 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: 15 - 60 min [Effectiveness Inhalation: 80%, Dermal: 80%] *A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. Please note that whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.*
Technical and organisational conditions and measures
• Pattern of use: Wide dispersive use • Pattern of exposure control: Direct handling • Contact level: Intermittent
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation *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.* • Gloves: Protective gloves according to EN 374 have to be worn. Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. [Effectiveness Dermal: 90%] • Eye protection: Eye protection to be worn to protect from adverse effects to the eyes *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.*

9.10.5.2. Exposure and risks for workers

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

Table 9.90. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.01 mg/m³ (MEASE: 1.02.01)	RCR = 0.071
Dermal, systemic, long term	6E-3 mg/kg bw/day (MEASE: 1.02.01)	RCR = 0.15
Combined routes, systemic, long-term		RCR = 0.221

Remarks on exposure data from external estimation tools:

MEASE 1.02.01
Explanations: Dermal, systemic, long term
For calculation of systemic exposure, the exposure estimate for total dermal loading as obtained in MEASE (reported in mg/day) is divided by a body weight of 70 kg for workers.

Risk characterisation

Further information on the risk characterisation for local effects or acute systemic effects via inhalation and via the dermal route and local effects to the eyes is given in Section 9.0.4.2.
Under the prescribed conditions of use, exposure is below the DNEL and local effects are not expected. Therefore, risks are adequately controlled.

9.11. Exposure scenario 11: Service life (professional worker) - Service life of treated articles in photography

Market sector: Photo-chemicals
Article categories:
AC 7: Metal articles
AC 13: Plastic articles

Environment contributing scenario(s):		
CS 1	Service life of treated articles in photography	ERC 11a
Worker contributing scenario(s):		
CS 2	Service life of treated articles in photography	PROC 21

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):
ES5: Use at industrial sites - Production of imaging and printing articles
ES6: Use at industrial sites - Production of printing plates
ES7: Use at industrial sites - Application of imaging and printing chemicals
ES8: Widespread use by professional workers - Use in photographic applications

Further description of the use:
Tetrachloroauric acid is used in photography to increase quality and durability. During the process, tetrachloroauric acid is transformed to gold metal.

Explanation on the approach taken for the ES:
The treated articles contain gold in metallic form, and concentrations of residual tetrachloroauric acid will be negligible and below the relevant threshold (<0.1%) triggering an exposure assessment.
Gold metal (EC 231-165-9) is registered in the 10-100 tpa tonnage band and does not meet the criteria to be classified as hazardous substance, hence no further exposure assessment is required

9.12. Exposure scenario 12: Service life (consumers) - Service life of treated articles

Market sector: Electrochemical and galvanic plating

Environment contributing scenario(s):		
CS 1	Service life of treated articles	ERC 11a
Consumer contributing scenario(s):		

CS 2	Service life of treated articles	AC 7

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):
ES9: Use at industrial sites - Use in electrochemical and galvanic plating
ES10: Widespread use by professional workers - Use in electrochemical and galvanic plating

Further description of the use:
After metal surface treatment, the treated articles are not expected to contain tetrachloroauric acid since the substance is transformed to gold metal during deposition on the article.

Explanation on the approach taken for the ES:
The treated articles contain gold in metallic form with >99.9% purity. As a result, the articles don't contain residual tetrachloroauric acid in concentrations above those triggering classification (concentrations <0.1%).
Gold metal (EC 231-165-9) is registered in the 10-100 tpa tonnage band and does not meet the criteria to be classified as hazardous substance, hence no further exposure assessment is required.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

This chapter describes why a separate risk characterisation related to combined exposure is not required and why any risks from potentially combined exposure sources is adequately controlled within the conditions of use prescribed in the exposure scenarios above. Combined exposure may result from any of the following scenarios:

1. Inhalation and dermal exposure route contributing to systemic effects at the same time,
2. More than just a single contributing occupational exposure scenario relevant for an individual worker,
3. Workers that are also exposed to tetrachloroauric acid in their free time (e.g. as member of the general population or as consumer).

These scenarios are considered in separate subchapters below:
1. Inhalation and dermal exposure route contributing to systemic effects at the same time
An RCR for systemic, combined exposure is always maintained below 1 in each of the ES.

2. More than just a single contributing occupational exposure scenario relevant for an individual worker
For aggregated exposure resulting from the applicability of more than just a single contributing worker scenario in a single work shift, it is noted that all exposure levels were derived for a full-shift exposure time and a safe use was demonstrated for each contributing scenario during manufacture, formulation and industrial uses with the sole exception of handling of the final product at manufacturing sites. For the latter, dedicated packaging personnel will not come into contact with the substances after the prescribed exposure/task duration. 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 for manufacture, formulation and industrial uses. Exposure duration is however reduced in the contributing exposure scenarios for the professional uses. Whenever a process step with reduced exposure duration needs to be conducted in addition to another process step, the exposure scenarios prescribe that the RCRs of these process steps need to be summed up and the result has to be below 1 to demonstrate safe use.

3. Workers that are also exposed to tetrachloroauric acid 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 applicable.

10.2. Environment (combined for all emission sources)

All exposure scenarios detailed in this document include estimates of background concentrations of total gold in water, sediment and soil (calculated using the EUSES model and the maximum proportion of the continental tonnage being manufactured and used in one region).

Annexes

1. Annex: References

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