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[1] ('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 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

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

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
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.