

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 08.03.2016

Version 6.3

SECTION 1. Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Catalogue No.	137000
Product name	Acetic acid (glacial) 100% suitable for biopharmaceutical production EMPROVE® bio Ph Eur,BP,JP,USP
REACH Registration Number	01-2119475328-30-XXXX
CAS-No.	64-19-7

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Pharmaceutical production In compliance with the conditions described in the annex to this safety data sheet.
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1.3 Details of the supplier of the safety data sheet

Company	Merck KGaA * 64271 Darmstadt * Germany * Phone:+49 6151 72-0
Responsible Department	LS-QHC * e-mail: prodsafe@merckgroup.com

1.4 Emergency telephone number **Please contact the regional company representation in your country.**

SECTION 2. Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Flammable liquid, Category 3, H226

Corrosive to metals, Category 1, H290

Skin corrosion, Category 1A, H314

For the full text of the H-Statements mentioned in this Section, see Section 16.

Classification (67/548/EEC or 1999/45/EC)

R10

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C Corrosive R35

For the full text of the R-phrases mentioned in this Section, see Section 16.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Danger

Hazard statements

H226 Flammable liquid and vapour.

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

Precautionary statements

Prevention

P210 Keep away from heat.

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

Response

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

P308 + P310 IF exposed or concerned: immediately call a POISON CENTER or doctor/ physician.

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word

Danger

Hazard statements

H314 Causes severe skin burns and eye damage.

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Precautionary statements

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P310 IF exposed or concerned: immediately call a POISON CENTER or doctor/ physician.

Contains: acetic acid

Index-No. 607-002-00-6

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	CH ₃ COOH	C ₂ H ₄ O ₂ (Hill)
Index-No.	607-002-00-6	
EC-No.	200-580-7	
Molar mass	60,05 g/mol	

Hazardous components (REGULATION (EC) No 1272/2008)

Chemical Name (Concentration)

CAS-No.	Registration number	Classification
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acetic acid (<= 100 %)

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

64-19-7	01-2119475328-30-	
	XXXX	Flammable liquid, Category 3, H226 Corrosive to metals, Category 1, H290 Skin corrosion, Category 1A, H314

For the full text of the H-Statements mentioned in this Section, see Section 16.

Hazardous components (1999/45/EC)

Chemical Name (Concentration)

CAS-No.	Classification
---------	----------------

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acetic acid ($\leq 100\%$)

64-19-7 R10

C, Corrosive; R35

For the full text of the R-phrases mentioned in this Section, see Section 16.

3.2 Mixture

Not applicable

SECTION 4. First aid measures

4.1 Description of first aid measures

General advice

First aider needs to protect himself.

After inhalation: fresh air. Call in physician.

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower. Call a physician immediately.

After eye contact: rinse out with plenty of water. Immediately call in ophthalmologist.

After swallowing: make victim drink water (two glasses at most), avoid vomiting (risk of perforation). Call a physician immediately. Do not attempt to neutralise.

4.2 Most important symptoms and effects, both acute and delayed

Irritation and corrosion, bronchitis, Shortness of breath, gastric spasms, Nausea, Vomiting,

Circulatory collapse, shock

Risk of corneal clouding.

Risk of blindness!

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water, Carbon dioxide (CO₂), Foam, Dry powder

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Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Combustible.

Vapours are heavier than air and may spread along floors.

Forms explosive mixtures with air at elevated temperatures.

Development of hazardous combustion gases or vapours possible in the event of fire.

Fire may cause evolution of:

Acetic acid vapours

5.3 Advice for firefighters

Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Further information

Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system. Remove container from danger zone and cool with water.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders: Protective equipment see section 8.

6.2 Environmental precautions

Do not let product enter drains. Risk of explosion.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills.

Observe possible material restrictions (see sections 7 and 10).

Take up with liquid-absorbent and neutralising material (e.g. Chemizorb® H⁺, Merck Art. No. 101595). Dispose of properly. Clean up affected area.

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6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Observe label precautions.

Advice on protection against fire and explosion

Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep away from heat and sources of ignition. Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature see product label.

7.3 Specific end use(s)

See exposure scenario in the Annex to this MSDS.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

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Derived No Effect Level (DNEL)

Worker DNEL, acute	Local effects	inhalation	25 mg/m ³
Worker DNEL, longterm	Local effects	inhalation	25 mg/m ³
Consumer DNEL, acute	Local effects	inhalation	25 mg/m ³
Consumer DNEL, longterm	Local effects	inhalation	25 mg/m ³

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	3,058 mg/l
PNEC Fresh water sediment	11,36 mg/kg
PNEC Marine water	0,3058 mg/l
PNEC Marine sediment	1,136 mg/kg
PNEC Aquatic intermittent release	30,58 mg/l
PNEC Sewage treatment plant	85 mg/l

8.2 Exposure controls

Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection

Tightly fitting safety goggles

Hand protection

full contact:

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Glove material: butyl-rubber
Glove thickness: 0,7 mm
Break through time: > 480 min

splash contact:

Glove material: natural latex
Glove thickness: 0,6 mm
Break through time: > 30 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 898 Butoject® (full contact), KCL 706 Lapren® (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

This recommendation applies only to the product stated in the safety data sheet(>,<)> supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Other protective equipment

Flame retardant antistatic protective clothing.

Respiratory protection

required when vapours/aerosols are generated.

Recommended Filter type: filter E-(P2)

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Environmental exposure controls

Do not let product enter drains.

Risk of explosion.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form liquid

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Colour	colourless
Odour	stinging
Odour Threshold	0,2 - 100,1 ppm
pH	2,5 at 50 g/l 20 °C
Melting point	17 °C
Boiling point/boiling range	116 - 118 °C at 1.013 hPa
Flash point	39 °C Method: c.c.
Evaporation rate	No information available.
Flammability (solid, gas)	Not applicable
Lower explosion limit	4 %(V)
Upper explosion limit	19,9 %(V)
Vapour pressure	15,4 hPa at 20 °C
Relative vapour density	2,07
Density	1,05 g/cm ³ at 20 °C
Relative density	No information available.

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Water solubility	602,9 g/l at 25 °C
Partition coefficient: n-octanol/water	log Pow: -0,17 (25 °C) (experimental) (ECHA) Bioaccumulation is not expected.
Auto-ignition temperature	No information available.
Decomposition temperature	Distillable in an undecomposed state at normal pressure.
Viscosity, dynamic	1,22 mPa.s at 20 °C
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

Ignition temperature	485 °C
Viscosity, kinematic	1,17 mm ² /s at 20 °C
Corrosion	May be corrosive to metals.

SECTION 10. Stability and reactivity

10.1 Reactivity

Vapour/air-mixtures are explosive at intense warming.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

Risk of explosion with:

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peroxi compounds, perchloric acid, fuming sulfuric acid, phosphorus halides, hydrogen peroxide,
chromium(VI) oxide, potassium permanganate, Peroxides, Strong oxidizing agents

Risk of ignition or formation of inflammable gases or vapours with:

Metals, Iron, Zinc, magnesium, Mild steel

Possible formation of:

Hydrogen

Violent reactions possible with:

strong alkalis, anhydrides, Aldehydes, alkali hydroxides, nonmetallic halides, ethanolamine,
Acetaldehyde, Alcohols, halogen-halogen compounds, chlorosulfonic acid, chromosulfuric acid,
Potassium hydroxide, Nitric acid

10.4 Conditions to avoid

Temperatures < 17 °C.

Heating.

10.5 Incompatible materials

various metals

10.6 Hazardous decomposition products

in the event of fire: See section 5.

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 Rat: 3.310 mg/kg

(RTECS)

Symptoms: If ingested, severe burns of the mouth and throat, as well as a danger of perforation
of the oesophagus and the stomach., Nausea, Vomiting, Risk of aspiration upon vomiting.,
Pulmonary failure possible after aspiration of vomit.

Acute inhalation toxicity

LCLO Rat: 39,95 mg/l; 4 h

(RTECS)

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Symptoms: mucosal irritations, Cough, Shortness of breath, Possible damages:, damage of respiratory tract, Pneumonia, bronchitis, Inhalation may lead to the formation of oedemas in the respiratory tract., Symptoms may be delayed.

Acute dermal toxicity

This information is not available.

Skin irritation

Rabbit

Result: Causes burns.

(IUCLID)

Causes severe burns.

Eye irritation

Rabbit

Result: Causes burns.

(IUCLID)

Causes serious eye damage.

Risk of blindness!

Risk of corneal clouding.

Sensitisation

This information is not available.

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

Mutagenicity (mammal cell test): chromosome aberration.

Result: negative

Method: OECD Test Guideline 473

Carcinogenicity

This information is not available.

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Reproductive toxicity

This information is not available.

Teratogenicity

Did not show teratogenic effects in animal experiments. (IUCLID)

Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

Systemic effects:

Shortness of breath, gastric spasms, shock, Circulatory collapse, acidosis

Possible damages:

Damage to:

Kidney

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

semi-static test LC50 *Oncorhynchus mykiss* (rainbow trout): > 300,8 mg/l; 96 h

OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates

EC5 *E.sulcatum*: 78 mg/l; 72 h

neutral (maximum permissible toxic concentration) (Lit.)

EC50 *Daphnia magna* (Water flea): 47 mg/l; 24 h

(Lit.)

Toxicity to algae

IC5 *Scenedesmus quadricauda* (Green algae): 4.000 mg/l; 16 h

(maximum permissible toxic concentration) (Lit.)

Toxicity to bacteria

EC5 *Pseudomonas putida*: 2.850 mg/l; 16 h

neutral (maximum permissible toxic concentration) (Lit.)

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microtox test EC50 Photobacterium phosphoreum: 11 mg/l; 15 min
(IUCLID)

12.2 Persistence and degradability

Biodegradability

99 %; 30 d

OECD Test Guideline 301D

(HSDB)

Readily biodegradable

95 %; 5 d

OECD Test Guideline 302B

Readily eliminated from water

Biochemical Oxygen Demand (BOD)

880 mg/g (5 d)

(Lit.)

Ratio BOD/ThBOD

BOD5 76 %

(IUCLID)

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: -0,17 (25 °C)

(experimental)

(ECHA) Bioaccumulation is not expected.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

12.6 Other adverse effects

Additional ecological information

Biological effects:

Harmful effect due to pH shift. Caustic even in diluted form.

Discharge into the environment must be avoided.

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SECTION 13. Disposal considerations

Waste treatment methods

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

SECTION 14. Transport information

Land transport (ADR/RID)

14.1 UN number UN 2789
14.2 Proper shipping name ACETIC ACID, GLACIAL
14.3 Class 8 (3)
14.4 Packing group II
14.5 Environmentally hazardous --
14.6 Special precautions for user yes
Tunnel restriction code D/E

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 UN number UN 2789
14.2 Proper shipping name ACETIC ACID, GLACIAL
14.3 Class 8 (3)
14.4 Packing group II
14.5 Environmentally hazardous --
14.6 Special precautions for user no

Sea transport (IMDG)

14.1 UN number UN 2789
14.2 Proper shipping name ACETIC ACID, GLACIAL
14.3 Class 8 (3)
14.4 Packing group II
14.5 Environmentally hazardous --

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14.6 Special precautions for user yes

EmS F-E S-C

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

SECTION 15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Major Accident Hazard SEVESO III

Legislation FLAMMABLE LIQUIDS

P5c

Quantity 1: 5.000 t

Quantity 2: 50.000 t

Occupational restrictions Take note of Dir 94/33/EC on the protection of young people at work.

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer not regulated

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC not regulated

Substances of very high concern (SVHC) This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of ≥ 0.1 % (w/w).

National legislation

Storage class 3

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

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SECTION 16. Other information

Full text of H-Statements referred to under sections 2 and 3.

H226 Flammable liquid and vapour.
H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.

Full text of R-phrases referred to under sections 2 and 3

R10 Flammable.
R35 Causes severe burns.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Danger

Hazard statements

H226 Flammable liquid and vapour.
H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.

Precautionary statements

Prevention

P210 Keep away from heat.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response


P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P308 + P310 IF exposed or concerned: immediately call a POISON CENTER or doctor/ physician.

Labelling (67/548/EEC or 1999/45/EC)


Symbol(s)  C Corrosive

R-phrase(s) 10-35 Flammable. Causes severe burns.

S-phrase(s) 23-26-45 Do not breathe vapour. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

EC-No. 200-580-7 EC Label

Reduced labelling (≤125 ml)

Symbol(s)  C Corrosive

R-phrase(s) 10-35 Flammable. Causes severe burns.

S-phrase(s) 26-45 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Contains: acetic acid

Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.

Regional representation

This information is given on the authorised Safety Data Sheet for your country.

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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EXPOSURE SCENARIO 1 (Industrial use)

1. Industrial use (Pharmaceutical production)

Sectors of end-use

SU 3 Industrial uses: Uses of substances as such or in preparations at industrial sites
SU 10 Formulation [mixing] of preparations and/ or re-packaging (excluding alloys)

Chemical product category

PC19 Intermediate

Process categories

PROC1 Use in closed process, no likelihood of exposure
PROC2 Use in closed, continuous process with occasional controlled exposure
PROC3 Use in closed batch process (synthesis or formulation)
PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact)
PROC8a Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities
PROC8b Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities
PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC15 Use as laboratory reagent

Environmental Release Categories

ERC1 Manufacture of substances
ERC2 Formulation of preparations
ERC4 Industrial use of processing aids in processes and products, not becoming part of articles
ERC6a Industrial use resulting in manufacture of another substance (use of intermediates)
ERC6b Industrial use of reactive processing aids

2. Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling worker exposure for: PROC1

Product characteristics

Concentration of the Substance in Covers the percentage of the substance in the product up to

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Mixture/Article	100 %.
Physical Form (at time of use)	High volatile liquid

Frequency and duration of use

Frequency of use	5 days/week
Frequency of use	8 hours/day

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor
------------------	--------

Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves tested to EN374.

2.2 Contributing scenario controlling worker exposure for: PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC15

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 100 %.
Physical Form (at time of use)	High volatile liquid

Frequency and duration of use

Frequency of use	5 days/week
Frequency of use	8 hours/day

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor with local exhaust ventilation (LEV)
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Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves tested to EN374.

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3. Exposure estimation and reference to its source

Environment

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.1	PROC1	longterm, inhalative, local	0,001	ECETOC TRA
2.2	PROC2	longterm, inhalative, local	0,1	ECETOC TRA
2.2	PROC3	longterm, inhalative, local	0,25	ECETOC TRA
2.2	PROC4	longterm, inhalative, local	0,2	ECETOC TRA
2.2	PROC5	longterm, inhalative, local	0,5	ECETOC TRA
2.2	PROC8a	longterm, inhalative, local	0,5	ECETOC TRA
2.2	PROC8b	longterm, inhalative, local	0,15	ECETOC TRA
2.2	PROC9	longterm, inhalative, local	0,5	ECETOC TRA
2.2	PROC15	longterm, inhalative, local	0,1	ECETOC TRA

The default parameters and -efficiencies of the applied exposure assessment model were used for the calculation (unless stated differently).

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).

For scaling of worker exposure assessments performed with ECETOC TRA, please consult the Merck tool SciDeEx® at www.merckmillipore.com/scideex.