

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 20.02.2018

Version 13.0

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Catalogue No.	100803
Product name	L(+)-Tartaric acid powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF,E 334
REACH Registration Number	01-2119537204-47-xxxx
CAS-No.	87-69-4

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

Identified uses	Pharmaceutical production, Cosmetic raw material 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

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Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2, H319

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Warning

Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

Response

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

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word

Warning

CAS-No. 87-69-4

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2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	HOOCCH(OH)CH(OH)COOH	C ₄ H ₆ O ₆ (Hill)
EC-No.	201-766-0	
Molar mass	150,08 g/mol	

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

Chemical name (Concentration)

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

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

87-69-4	01-2119537204-47-	
	xxxx	Eye irritation, Category 2, H319

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

3.2 Mixture

Not applicable

SECTION 4. First aid measures

4.1 Description of first aid measures

After inhalation: fresh air.

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

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

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4.2 Most important symptoms and effects, both acute and delayed

irritant effects, Diarrhoea

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, Foam, Carbon dioxide (CO₂), Dry powder

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.

Forms explosive mixtures with air on intense heating.

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

Vapours are heavier than air and may spread along floors.

5.3 Advice for firefighters

Special protective equipment for firefighters

In the event of fire, wear self-contained breathing apparatus.

Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders:

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Protective equipment see section 8.

6.2 Environmental precautions

Do not let product enter drains.

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 dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

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.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

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, longterm	Systemic effects	dermal	2,9 mg/kg Body weight
Worker DNEL, longterm	Systemic effects	inhalation	5,2 mg/m ³
Consumer DNEL, longterm	Systemic effects	dermal	1,5 mg/kg Body weight
Consumer DNEL, longterm	Systemic effects	inhalation	1,3 mg/m ³
Consumer DNEL, longterm	Systemic effects	oral	8,1 mg/kg Body weight

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	0,3125 mg/l
PNEC Marine water	0,3125 mg/l
PNEC Aquatic intermittent release	0,514 mg/l
PNEC Sewage treatment plant	10 mg/l
PNEC Sediment	1,141 mg/kg
PNEC Marine sediment	1,141 mg/kg
PNEC Soil	0,0449 mg/kg

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.

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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

Safety glasses

Hand protection

full contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm
Break through time:	480 min

splash contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm
Break through time:	480 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 741 Dermatril® L (full contact), KCL 741 Dermatril® L (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

protective clothing

Respiratory protection

required when dusts are generated.

Recommended Filter type: Filter P 2 (acc. to DIN 3181) for solid and liquid particles of harmful substances

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective

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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.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	solid
Colour	white
Odour	odourless
Odour Threshold	Not applicable
pH	ca. 1,6 at 100 g/l 25 °C
Melting point	168 - 170 °C
Boiling point/boiling range	Not applicable
Flash point	210 °C
Evaporation rate	No information available.
Flammability (solid, gas)	The product is not flammable. NF T 20-042
Lower explosion limit	No information available.

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Upper explosion limit	No information available.
Vapour pressure	< 5 Pa at 20 °C Method: NF T 20-048 < 5 Pa at 50 °C Method: NF T 20-048
Relative vapour density	No information available.
Density	1,76 g/cm ³ at 20 °C
Relative density	No information available.
Water solubility	1.390 g/l at 20 °C
Partition coefficient: n-octanol/water	log Pow: -1,91 (20 °C) OECD Test Guideline 107 Bioaccumulation is not expected.
Auto-ignition temperature	375 °C at 1.015 hPa Method: NF T 20-036
Decomposition temperature	> 170 °C
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.

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Oxidizing properties none

9.2 Other data

none

SECTION 10. Stability and reactivity

10.1 Reactivity

Forms explosive mixtures with air on intense heating.

A range from approx. 15 Kelvin below the flash point is to be rated as critical.

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Exothermic reaction with:

Strong oxidizing agents, silver, hydrogen peroxide

alkaline substances

with

Water

Risk of explosion with:

silver salt

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

Fluorine

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

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Product name L(+)-Tartaric acid powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF,E 334

no information available

10.6 Hazardous decomposition products

no information available

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

Symptoms: Diarrhoea

Acute inhalation toxicity

Symptoms: Possible damages:, mucosal irritations

Acute dermal toxicity

LD50 Rat: > 2.000 mg/kg

OECD Test Guideline 402

Skin irritation

Rabbit

Result: No skin irritation

OECD Test Guideline 404

slight irritation

Eye irritation

Causes serious eye irritation.

Sensitisation

Local lymph node assay (LLNA) Mouse

Result: negative

Method: OECD Test Guideline 429

Germ cell mutagenicity

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Genotoxicity in vivo

dominant lethal test

Rat

male and female

Oral

Result: negative

Method: OECD Test Guideline 478

Chromosome aberration test

Rat

male

Oral

Result: negative

Method: OECD Test Guideline 475

Genotoxicity in vitro

Ames test

Result: negative

(Lit.)

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

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.

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11.2 Further information

Substances which occur in nature

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

static test LC50 Danio rerio (zebra fish): > 100 mg/l; 96 h

Analytical monitoring: yes

OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia (water flea): 135 mg/l; 24 h

(Lit.)

Toxicity to bacteria

static test EC50 activated sludge: > 1.000 mg/l; 3 h

OECD Test Guideline 209

12.2 Persistence and degradability

Theoretical oxygen demand (ThOD)

533 mg/g

(Lit.)

Ratio BOD/ThBOD

BOD5 56 %

(Lit.)

Ratio COD/ThBOD

98 %

(Lit.)

12.3 Bioaccumulative potential

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Partition coefficient: n-octanol/water

log Pow: -1,91 (20 °C)

OECD Test Guideline 107

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

Discharge into the environment must be avoided.

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 - 14.6 Not classified as dangerous in the meaning of transport regulations.

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

Sea transport (IMDG)

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14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

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 Not applicable

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 10 - 13

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.

H319 Causes serious eye irritation.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Warning

Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

Response

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

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

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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, Cosmetic raw material)

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

PC39 Cosmetics, personal care products

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

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

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2.1 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3

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)	Solid, high dustiness

Frequency and duration of use

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

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor with good general ventilation
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Conditions and measures related to personal protection, hygiene and health evaluation

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Tightly fitting safety goggles

Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice	Wear suitable coveralls to prevent exposure to the skin.
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2.2 Contributing scenario controlling worker exposure for: 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)	Solid, high dustiness

Frequency and duration of use

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

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor with local exhaust ventilation (LEV)
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Remarks Reduction factor for local exhaust ventilation (LEV) has been used for the calculation of dermal exposure estimates.

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

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Tightly fitting safety goggles

Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice Wear suitable coveralls to prevent exposure to the skin.

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, systemic	< 0,01	ECETOC TRA 3
		longterm, dermal, systemic	< 0,01	ECETOC TRA 3
		longterm, combined, systemic	< 0,01	
2.1	PROC2	longterm, inhalative, systemic	0,19	ECETOC TRA 3
		longterm, dermal, systemic	0,02	ECETOC TRA 3
		longterm, combined, systemic	0,22	
2.1	PROC3	longterm, inhalative, systemic	0,19	ECETOC TRA 3
		longterm, dermal, systemic	0,01	ECETOC TRA 3
		longterm, combined, systemic	0,20	

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2.2	PROC4	longterm, inhalative, systemic	0,48	ECETOC TRA, modified
		longterm, dermal, systemic	0,01	ECETOC TRA, modified
		longterm, combined, systemic	0,49	
2.2	PROC5	longterm, inhalative, systemic	0,48	ECETOC TRA, modified
		longterm, dermal, systemic	0,02	ECETOC TRA, modified
		longterm, combined, systemic	0,5	
2.2	PROC8a	longterm, inhalative, systemic	0,96	ECETOC TRA, modified
		longterm, dermal, systemic	0,02	ECETOC TRA, modified
		longterm, combined, systemic	0,99	
2.2	PROC8b	longterm, inhalative, systemic	0,24	ECETOC TRA, modified
		longterm, dermal, systemic	0,01	ECETOC TRA, modified
		longterm, combined, systemic	0,25	
2.2	PROC9	longterm, inhalative, systemic	0,38	ECETOC TRA, modified
		longterm, dermal, systemic	0,01	ECETOC TRA, modified
		longterm, combined, systemic	0,4	
2.2	PROC15	longterm, inhalative, systemic	0,1	ECETOC TRA, modified
		longterm, dermal, systemic	< 0,01	ECETOC TRA, modified
		longterm, combined, systemic	0,1	

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

For (other) local effects risk management measures are based on qualitative risk characterisation.

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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.

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EXPOSURE SCENARIO 2 (Professional use, Consumer use)

1. Professional use, Consumer use (Pharmaceutical production, Cosmetic raw material)

Sectors of end-use

SU 22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Chemical product category

PC39 Cosmetics, personal care products

Process categories

PROC15 Use as laboratory reagent

Environmental Release Categories

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

ERC8a Wide dispersive indoor use of processing aids in open systems

ERC8d Wide dispersive outdoor use of processing aids in open systems

2. Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling worker exposure for: 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)	Solid, high dustiness

Frequency and duration of use

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

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor with local exhaust ventilation (LEV)
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Remarks Reduction factor for local exhaust ventilation (LEV) has been used for the calculation of dermal exposure estimates.

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

Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls. Tightly fitting safety goggles

Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice Wear suitable coveralls to prevent exposure to the skin.

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	PROC15	longterm, inhalative, systemic	0,19	ECETOC TRA, modified
		longterm, dermal, systemic	< 0,01	ECETOC TRA, modified
		longterm, combined, systemic	0,19	

In accordance with REACH Article 14(5b), exposure estimations and risk characterizations for human health do not need to be performed for uses of substances in cosmetic products which are under the scope of Directive 76/768/EEC.

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

For (other) local effects risk management measures are based on qualitative risk characterisation.

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

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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.