

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 20.07.2018

Version 12.2

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

1.1 Product identifier

Catalogue No.	108421
Product name	Titriplex® III (ethylenedinitrilotetraacetic acid disodium salt dihydrate) EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP
REACH Registration Number	01-2119486775-20-XXXX
CAS-No.	6381-92-6

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

Identified uses	Pharmaceutical production, Cosmetic raw material, Biocidal product 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.
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SECTION 2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4, Inhalation, H332

Specific target organ toxicity - repeated exposure, Category 2, Inhalation, Respiratory Tract, H373

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

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Warning

Hazard statements

H332 Harmful if inhaled.

H373 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled.

Precautionary statements

Response

P314 Get medical advice/ attention if you feel unwell.

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word

Warning

Contains: Disodium dihydrogen ethylenediaminetetraacetate dihydrate

CAS-No. 6381-92-6

2.3 Other hazards

None known.

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SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	$C_{10}H_{14}N_2O_8 \cdot 2Na \cdot 2H_2O$	$C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$ (Hill)
EC-No.	205-358-3	
Molar mass	372,24 g/mol	

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

Chemical name (Concentration)

CAS-No.	Registration number	Classification
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Disodium dihydrogen ethylenediaminetetraacetate dihydrate ($\leq 100\%$)

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

6381-92-6	01-2119486775-20-XXXX	Acute toxicity, Category 4, H332 Specific target organ toxicity - repeated exposure, Category 2, H373
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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. Call in physician.

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. 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

We have no description of any symptoms of toxicity.

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.

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

Fire may cause evolution of:

nitrogen oxides

5.3 Advice for firefighters

Special protective equipment for firefighters

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

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.

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

Work under hood. Do not inhale substance/mixture.

Observe label precautions.

Hygiene measures

Change contaminated clothing. Preventive skin protection recommended. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

No aluminium, tin, or zinc containers.

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.

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SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Derived No Effect Level (DNEL)

Worker DNEL, acute	Local effects	inhalation	3 mg/m ³
Worker DNEL, longterm	Local effects	inhalation	1,5 mg/m ³
Consumer DNEL, acute	Local effects	inhalation	1,2 mg/m ³
Consumer DNEL, longterm	Local effects	inhalation	0,6 mg/m ³
Consumer DNEL, longterm	Systemic effects	oral	25 mg/kg Body weight

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	2,2 mg/l
PNEC Marine water	0,22 mg/l
PNEC Aquatic intermittent release	1,2 mg/l
PNEC Sewage treatment plant	43 mg/l
PNEC Soil	0,72 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.

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.

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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 devices are carried out according to the instructions of the producer. These measures have to be properly documented.

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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	crystals
Colour	white
Odour	odourless
Odour Threshold	Not applicable
pH	4 - 5 at 50 g/l 20 °C
Melting point	110 °C Elimination of water of crystallisation
Boiling point/boiling range	Not applicable, (decomposition)
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.

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Vapour pressure	No information available.
Relative vapour density	No information available.
Density	No information available.
Relative density	No information available.
Water solubility	100 g/l at 20 °C
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	255 °C
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

Bulk density	ca.700 kg/m ³
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SECTION 10. Stability and reactivity

10.1 Reactivity

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

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releases water of crystallisation when heated.

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

10.3 Possibility of hazardous reactions

Violent reactions possible with:

Strong oxidizing agents

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

Aluminium, Copper, Copper alloys, Nickel, Zinc

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: 2.800 mg/kg

OECD Test Guideline 401

(anhydrous substance)

Acute inhalation toxicity

Acute toxicity estimate: 1,6 mg/l; dust/mist

Expert judgement

Acute dermal toxicity

This information is not available.

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Skin irritation

Rabbit

Result: No irritation

OECD Test Guideline 404

(anhydrous substance)

Eye irritation

Rabbit

Result: No eye irritation

(ECHA) (anhydrous substance)

Sensitisation

This information is not available.

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

(anhydrous substance) (Lit.)

Mouse lymphoma test

Result: negative

(ECHA) (anhydrous substance)

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

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Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Exposure routes: Inhalation

Target Organs: Respiratory Tract

Repeated dose toxicity

Rat

male

Inhalation

aerosol

5 d

daily

LOAEL: 0,03 mg/l

OECD Test Guideline 412

Target Organs: Lungs, larynx

Rat

male and female

Inhalation

dust/mist

90 d

daily

NOAEL: 0,003 mg/l

OECD Test Guideline 413

Target Organs: larynx

Rat

male

Oral

13 Weeks

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daily

NOAEL: $\geq$ 500 mg/kg

(ECHA)

Aspiration hazard

This information is not available.

11.2 Further information

After absorption:

disturbed electrolyte balance.

After uptake of large quantities:

Damage to:

Kidney

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

LC50 *Poecilia reticulata* (guppy): ca. 320 mg/l; 96 h

(anhydrous substance) (IUCLID)

Toxicity to bacteria

EC50 activated sludge: 403 mg/l; 3 h

OECD Test Guideline 209

EC50 *Pseudomonas putida*: 56 mg/l; 8 h

(anhydrous substance) (IUCLID)

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

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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.
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Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 - 14.6	Not classified as dangerous in the meaning of transport regulations.
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Sea transport (IMDG)

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

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Occupational restrictions	Take note of Dir 94/33/EC on the protection of young people at work. Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.
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Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	not regulated
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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
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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 $\geq 0.1\%$ (w/w).
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National legislation

Storage class	10 - 13
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15.2 Chemical safety assessment

A Chemical Safety Assessment has been carried out according to regulation (EC) No. 1907/2006 (REACH) for this substance.

SECTION 16. Other information

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

H332	Harmful if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure if inhaled.

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Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Warning

Hazard statements

H332 Harmful if inhaled.

H373 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled.

Precautionary statements

Response

P314 Get medical advice/ attention if you feel unwell.

Contains: Disodium dihydrogen ethylenediaminetetraacetate dihydrate

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.

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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, Biocidal product)

Sectors of end-use

<i>SU 3</i>	Industrial uses: Uses of substances as such or in preparations at industrial sites
<i>SU 9</i>	Manufacture of fine chemicals
<i>SU 10</i>	Formulation [mixing] of preparations and/ or re-packaging (excluding alloys)

Chemical product category

<i>PC 8</i>	Biocidal products (e.g. Disinfectants, pest control)
<i>PC 19</i>	Intermediate
<i>PC 21</i>	Laboratory chemicals
<i>PC 28</i>	Perfumes, fragrances
<i>PC 39</i>	Cosmetics, personal care products

Process categories

<i>PROC 1</i>	Use in closed process, no likelihood of exposure
<i>PROC 2</i>	Use in closed, continuous process with occasional controlled exposure
<i>PROC 3</i>	Use in closed batch process (synthesis or formulation)
<i>PROC 4</i>	Use in batch and other process (synthesis) where opportunity for exposure arises
<i>PROC 5</i>	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact)
<i>PROC 8a</i>	Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities
<i>PROC 8b</i>	Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities
<i>PROC 9</i>	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
<i>PROC 10</i>	Roller application or brushing
<i>PROC 14</i>	Production of preparations or articles by tableting, compression, extrusion, pelletisation
<i>PROC 15</i>	Use as laboratory reagent

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Environmental Release Categories

<i>ERC1</i>	Manufacture of substances
<i>ERC2</i>	Formulation of preparations
<i>ERC4</i>	Industrial use of processing aids in processes and products, not becoming part of articles
<i>ERC6a</i>	Industrial use resulting in manufacture of another substance (use of intermediates)
<i>ERC6b</i>	Industrial use of reactive processing aids
<i>ERC8a</i>	Wide dispersive indoor use of processing aids in open systems

2. Contributing scenarios: Operational conditions and risk management measures

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

Frequency and duration of use

Frequency of use	8 hours/day
Remarks	Long term
Frequency of use	< 15 minutes/day
Remarks	Short term
Frequency of use	5 days/week

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor without local exhaust ventilation (LEV)
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Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves tested to EN374.

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, PROC14

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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, medium dustiness

Frequency and duration of use

Frequency of use	8 hours/day
Remarks	Long term
Frequency of use	< 15 minutes/day
Remarks	Short term
Frequency of use	5 days/week

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor with local exhaust ventilation (LEV)
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Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves tested to EN374.

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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2.3 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC14, PROC15

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 55 %.
Physical Form (at time of use)	Solid substance, Aqueous solution

Frequency and duration of use

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

Other operational conditions affecting workers exposure

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Outdoor / Indoor

Indoor without local exhaust ventilation (LEV)

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

Wear suitable gloves tested to EN374.

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	acute, inhalative, local	< 0,01	ECETOC TRA 3, Solid
		longterm, inhalative, local	< 0,01	ECETOC TRA 3, Solid
2.1	PROC2	acute, inhalative, local	0,17	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,33	ECETOC TRA 3, Solid
2.1	PROC3	acute, inhalative, local	0,33	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,67	ECETOC TRA 3, Solid
2.1	PROC15	acute, inhalative, local	0,17	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,33	ECETOC TRA 3, Solid

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2.2	PROC4	acute, inhalative, local	0,17	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,33	ECETOC TRA 3, Solid
2.2	PROC5	acute, inhalative, local	0,17	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,33	ECETOC TRA 3, Solid
2.2	PROC8a	acute, inhalative, local	0,17	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,33	ECETOC TRA 3, Solid
2.2	PROC8b	acute, inhalative, local	0,17	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,33	ECETOC TRA 3, Solid
2.2	PROC9	acute, inhalative, local	0,17	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,33	ECETOC TRA 3, Solid
2.2	PROC14	acute, inhalative, local	0,03	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,07	ECETOC TRA 3, Solid
2.3	PROC1	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid
2.3	PROC2	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid
2.3	PROC3	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid
2.3	PROC5	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid
2.3	PROC8a	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid
2.3	PROC8b	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid
2.3	PROC9	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid
2.3	PROC10	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid
2.3	PROC14	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid
2.3	PROC15	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid

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

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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;

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Product name	Titriplex® III (ethylenedinitrilotetraacetic acid disodium salt dihydrate)
	EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP

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)

1. Professional use Pharmaceutical production, Cosmetic raw material, Biocidal product)

Sectors of end-use

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

Chemical product category

PC8 Biocidal products (e.g. Disinfectants, pest control)

PC21 Laboratory chemicals

PC39 Cosmetics, personal care products

Process categories

PROC15 Use as laboratory reagent

Environmental Release Categories

ERC2 Formulation of preparations

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, medium dustiness

Frequency and duration of use

Frequency of use	8 hours/day
Remarks	Long term
Frequency of use	< 15 minutes/day

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Remarks	Short term
Frequency of use	5 days/week

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor without local exhaust ventilation (LEV)
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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: PROC15

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 40 %.
Physical Form (at time of use)	Solid substance, Aqueous solution

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 without local exhaust ventilation (LEV)
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Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves tested to EN374.

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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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).

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Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.1	PROC15	acute, inhalative, local	0,17	ECETOC TRA 3, Solid
		longterm, inhalative, local	0,33	ECETOC TRA 3, Solid
2.2	PROC15	longterm, inhalative, local	< 1	Qualitative assessment used to conclude safe use., Liquid

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).

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EXPOSURE SCENARIO 3 (Consumer use)

1. Consumer use Pharmaceutical production, Cosmetic raw material, Biocidal product)

Sectors of end-use

SU 21 Consumer uses: Private households (= general public = consumers)

Chemical product category

PC8 Biocidal products (e.g. Disinfectants, pest control)

PC39 Cosmetics, personal care products

Environmental Release Categories

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

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

A chemical safety assessment was performed according REACH Article 14(3) and Annex I, section 1 (Human Health Hazard Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

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.

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

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