

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 20.07.2018

Version 15.2

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

Catalogue No. 106303

Product name di-Sodium tetraborate decahydrate EMPROVE® ESSENTIAL Ph
Eur,BP,JP,NF

REACH Registration Number 01-2119490790-32-XXXX

CAS-No. 1303-96-4

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.

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)**

Eye irritation, Category 2, H319

Reproductive toxicity, Category 1B, H360FD

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

Danger

Hazard statements

H360FD May damage fertility. May damage the unborn child.

H319 Causes serious eye irritation.

Precautionary statements

Prevention

P201 Obtain special instructions before use.

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.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Restricted to professional users.

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word

Danger

Hazard statements

H360FD May damage fertility. May damage the unborn child.

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Precautionary statements

P201 Obtain special instructions before use.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Index-No. 005-011-01-1

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	Na ₂ B ₄ O ₇ *10 H ₂ O	B ₄ Na ₂ O ₇ *10H ₂ O (Hill)
Index-No.	005-011-01-1	
EC-No.	215-540-4	
Molar mass	381,32 g/mol	

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

Chemical name (Concentration)

CAS-No.	Registration number	Classification
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disodium tetraborate decahydrate (<= 100 %)

PBT/vPvB: Not applicable for inorganic substances

1303-96-4	01-2119490790-32-XXXX	Eye irritation, Category 2, H319 Reproductive toxicity, Category 1B, H360FD
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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.

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

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

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

4.2 Most important symptoms and effects, both acute and delayed

irritant effects

The following applies to boron compounds in general: resorption is followed by nausea and vomiting, agitation, spasms, CNS disorders, cardiovascular disorders.

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

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Not combustible.

Ambient fire may liberate hazardous 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

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

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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: Protective equipment see section 8.

6.2 Environmental precautions

Do not empty into 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

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

Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorised persons.

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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	2,52 mg/m ³ (Expressed as Boron)
Worker DNEL, longterm	Systemic effects	dermal	68 mg/kg Body weight (Expressed as Boron)
Worker DNEL, longterm	Systemic effects	inhalation	1,45 mg/m ³ (Expressed as Boron)
Worker DNEL, longterm	Local effects	inhalation	2,52 mg/m ³ (Expressed as Boron)
Consumer DNEL, acute	Systemic effects	oral	0,17 mg/kg Body weight (Expressed as Boron)
Consumer DNEL, acute	Local effects	inhalation	2,52 mg/m ³ (Expressed as Boron)
Consumer DNEL, longterm	Systemic effects	dermal	34,3 mg/kg Body weight (Expressed as Boron)
Consumer DNEL, longterm	Systemic effects	inhalation	0,73 mg/m ³ (Expressed as Boron)
Consumer DNEL, longterm	Systemic effects	oral	0,17 mg/kg Body weight (Expressed as Boron)
Consumer DNEL, longterm	Local effects	inhalation	2,52 mg/m ³ (Expressed as Boron)

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	2,9 mg/l (Expressed as Boron)
PNEC Marine water	2,9 mg/l (Expressed as Boron)
PNEC Aquatic intermittent release	13,7 mg/l (Expressed as Boron)
PNEC Sewage treatment plant	10 mg/l (Expressed as Boron)
PNEC Soil	5,7 mg/kg (Expressed as Boron)

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 3 (acc. to DIN 3181) for solid and liquid particles of toxic and very toxic substances

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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 empty into 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	9,2 at 47 g/l 20 °C
Melting point	75 °C Elimination of water of crystallisation
Boiling point	No information available.
Flash point	Not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	The product is not flammable.

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Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapour pressure	0,213 hPa at 20 °C
Relative vapour density	No information available.
Density	1,72 g/cm ³ at 20 °C
Relative density	No information available.
Water solubility	49,74 g/l at 20 °C
Partition coefficient: n- octanol/water	Not applicable
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

Ignition temperature	not combustible
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Bulk density ca.750 kg/m³

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

releases water of crystallisation when heated.

10.3 Possibility of hazardous reactions

Violent reactions possible with:

strong oxidising agents, Acids, metallic salts

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

no information available

10.6 Hazardous decomposition products

no information available

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 Rat: > 2.500 mg/kg

OECD Test Guideline 401

The value is given in analogy to the following substances: disodium tetraborate

Acute inhalation toxicity

LC50 Rat: > 2,04 mg/l; 4 h ; dust/mist

OECD Test Guideline 403

The value is given in analogy to the following substances: disodium tetraborate pentahydrate

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Symptoms: Possible damages:, mucosal irritations, Irritation symptoms in the respiratory tract.

Acute dermal toxicity

LD50 Rabbit: > 2.000 mg/kg

(ECHA) The value is given in analogy to the following substances: disodium tetraborate pentahydrate

Skin irritation

Rabbit

Result: No irritation

(ECHA) The value is given in analogy to the following substances: disodium tetraborate pentahydrate

Eye irritation

Rabbit

Result: Causes serious eye irritation.

OECD Test Guideline 405

Causes serious eye irritation.

Sensitisation

Buehler Test Guinea pig

Result: negative

Method: OECD Test Guideline 406

The value is given in analogy to the following substances: disodium tetraborate pentahydrate

Germ cell mutagenicity

This information is not available.

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

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Teratogenicity

This information is not available.

CMR effects

Teratogenicity:

May damage the unborn child.

Reproductive toxicity:

May damage fertility.

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

Absorption via:

Gastrointestinal tract, Mucous membranes

The following applies to boron compounds in general: resorption is followed by nausea and vomiting, agitation, spasms, CNS disorders, cardiovascular disorders.

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 *Carassius auratus* (goldfish): 630 mg/l; 72 h

(IUCLID)

Toxicity to daphnia and other aquatic invertebrates

EC50 *Daphnia magna* (Water flea): 1.085 - 1.402 mg/l; 48 h

(IUCLID)

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Toxicity to algae

IC50 *Desmodesmus subspicatus* (green algae): 158 mg/l; 96 h
(anhydrous substance) (IUCLID)

Toxicity to bacteria

EC0 *Pseudomonas putida*: 15,8 mg/l; 16 h
(anhydrous substance) (IUCLID)

12.2 Persistence and degradability

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water

Not applicable

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB: Not applicable for inorganic substances

12.6 Other adverse effects

Additional ecological information

Herbicide

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 - 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)

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

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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.

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 contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 59 above the respective regulatory concentration limit of > 0.1 % (w/w).

Contains: disodium tetraborate decahydrate

National legislation

Storage class 6.1 D

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.

H319 Causes serious eye irritation.
H360FD May damage fertility. May damage the unborn child.

Training advice

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Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Danger

Hazard statements

H319 Causes serious eye irritation.

H360 May damage fertility or the unborn child.

Precautionary statements

Prevention

P201 Obtain special instructions before use.

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.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Further information

Restricted to professional users.

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)
PROC14 Production of preparations or articles by tableting, compression, extrusion, pelletisation
PROC15 Use as laboratory reagent
PROC22 Potentially closed processing operations with minerals/ metals at elevated temperature; Industrial setting
PROC23 Open processing and transfer operations with minerals/ metals at elevated temperature

Environmental Release Categories

ERC2 Formulation of preparations

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<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

2. Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling environmental exposure for: ERC2

Amount used

Annual amount per site	950 t
Remarks	Expressed as, Boron

Environment factors not influenced by risk management

Dilution Factor (River)	10
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Other given operational conditions affecting environmental exposure

Number of emission days per year	200
Emission or Release Factor: Air	0,0004 %
Emission or Release Factor: Water	0,008 %

Technical conditions and measures / Organizational measures

Air	exhaust air scrubber Fabric filter Air cyclones for dust collection Electrostatic precipitation for dust collection.
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Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant	Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	2.000 m3/d
Percentage removed from waste water	0 %
Remarks	The concentration in the sewage treatment plant should be below the respective PNEC STP

Conditions and measures related to external treatment of waste for disposal

Disposal methods	Dispose of as hazardous waste in compliance with local and national regulations.
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Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice	Sweep up or vacuum up spillage and collect in suitable container for disposal.
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2.2 Contributing scenario controlling environmental exposure for: ERC4

Amount used

Annual amount per site	14 t
Remarks	Expressed as, Boron

Environment factors not influenced by risk management

Dilution Factor (River)	10
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Other given operational conditions affecting environmental exposure

Number of emission days per year	365
Emission or Release Factor: Air	0,037 %
Emission or Release Factor: Water	100 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant	Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	2.000 m3/d
Percentage removed from waste water	0 %
Remarks	The concentration in the sewage treatment plant should be below the respective PNEC STP

Conditions and measures related to external treatment of waste for disposal

Disposal methods	Dispose of as hazardous waste in compliance with local and national regulations.
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Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice	Sweep up or vacuum up spillage and collect in suitable container for disposal.
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2.3 Contributing scenario controlling environmental exposure for: ERC6a, ERC6b

Amount used

Annual amount per site	190 t
Remarks	Expressed as, Boron

Environment factors not influenced by risk management

Dilution Factor (River)	10
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Other given operational conditions affecting environmental exposure

Number of emission days per year	100
Emission or Release Factor: Air	0,037 %
Emission or Release Factor: Water	0,06 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant	Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	2.000 m3/d
Percentage removed from waste water	0 %
Remarks	The concentration in the sewage treatment plant should be below the respective PNEC STP

Conditions and measures related to external treatment of waste for disposal

Disposal methods	Dispose of as hazardous waste in compliance with local and national regulations.
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Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice	Sweep up or vacuum up spillage and collect in suitable container for disposal.
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2.4 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC22, PROC23

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

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. Wear suitable gloves tested to EN374.
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2.5 Contributing scenario controlling worker exposure for: PROC4, PROC14

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 25 %.
Physical Form (at time of use)	Solid, high dustiness

Frequency and duration of use

Frequency of use	< 15 minutes/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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Conditions and measures related to personal protection, hygiene and health evaluation

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. Wear
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suitable gloves tested to EN374.

2.6 Contributing scenario controlling worker exposure for: PROC5

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)

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

Respirator with a half face mask 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. Wear suitable gloves tested to EN374.

2.7 Contributing scenario controlling worker exposure for: PROC8a, PROC8b, PROC9

Product characteristics

Concentration of the Substance in Mixture/Article Covers the percentage of the substance in the product up to 25 %.

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

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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

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. Wear suitable gloves tested to EN374.
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2.8 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	< 1 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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Conditions and measures related to personal protection, hygiene and health evaluation

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. Wear suitable gloves tested to EN374.
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3. Exposure estimation and reference to its source

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Catalogue No. 106303
 Product name di-Sodium tetraborate decahydrate EMPROVE® ESSENTIAL Ph
 Eur,BP,JP,NF

Environment

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC2		Fresh water	0,68	EUSES
			Soil	< 0,01	EUSES
2.2	ERC4		Fresh water	0,68	EUSES
			Soil	0,01	EUSES
2.3	ERC6a, ERC6b		Fresh water	0,68	EUSES
			Soil	0,15	EUSES

Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.4	PROC1, PROC2, PROC3, PROC22, PROC23	longterm, inhalative, systemic	0,06	MEASE
		longterm, dermal, systemic	< 0,01	MEASE
		longterm, combined, systemic	0,06	
2.5	PROC4, PROC14	longterm, inhalative, systemic	0,02	MEASE
		longterm, dermal, systemic	0,02	ART
		longterm, combined, systemic	0,04	
2.6	PROC5	longterm, inhalative, systemic	0,14	MEASE
		longterm, dermal, systemic	< 0,01	Measured data
		longterm, combined, systemic	0,14	
2.7	PROC8a, PROC8b, PROC9	longterm, inhalative, systemic	0,69	MEASE
		longterm, dermal, systemic	0,14	ART
		longterm, combined, systemic	0,83	
2.8	PROC15	longterm, inhalative, systemic	0,11	MEASE
		longterm, dermal, systemic	< 0,01	Measured data
		longterm, combined, systemic	0,11	

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

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Product name	di-Sodium tetraborate decahydrate EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF

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 environmental exposure assessments, please refer to the ARCHE tool at www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool.

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EXPOSURE SCENARIO 2 (Professional use)

1. Professional 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

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

2.1 Contributing scenario controlling environmental exposure for: ERC8a, ERC8d

Amount used

Annual amount for wide disperse uses 35000 t
Remarks Expressed as, Boron

Environment factors not influenced by risk management

Dilution Factor (River) 10

Other given operational conditions affecting environmental exposure

Number of emission days per year 365
Emission or Release Factor: Water 100 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent 2.000 m3/d
Percentage removed from waste 0 %

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Catalogue No.	106303
Product name	di-Sodium tetraborate decahydrate EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF

water

Remarks	The concentration in the sewage treatment plant should be below the respective PNEC STP
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Conditions and measures related to external treatment of waste for disposal

Disposal methods	Dispose of as hazardous waste in compliance with local and national regulations.
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Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice	Sweep up or vacuum up spillage and collect in suitable container for disposal.
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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 100 %.
Physical Form (at time of use)	Solid, high dustiness

Frequency and duration of use

Frequency of use	< 1 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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Conditions and measures related to personal protection, hygiene and health evaluation

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. Wear suitable gloves tested to EN374.
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3. Exposure estimation and reference to its source

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Catalogue No. 106303
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Eur,BP,JP,NF

Environment

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC8a, ERC8d		Fresh water	0,35	EUSES
			Sewage treatment plant	0,96	EUSES

Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.2	PROC15	longterm, inhalative, systemic	0,11	MEASE
		longterm, dermal, systemic	< 0,01	Measured data
		longterm, combined, systemic	0,11	

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 environmental exposure assessments, please refer to the ARCHE tool at www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool.

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Eur,BP,JP,NF

EXPOSURE SCENARIO 3 (Consumer use)

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

Sectors of end-use

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

Chemical product category

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

2.1 Contributing scenario controlling environmental exposure for: ERC8a, ERC8d: Wide dispersive indoor use of processing aids in open systems, Wide dispersive outdoor use of processing aids in open systems

Amount used

Annual amount for wide disperse uses 35000 t
Remarks Expressed as, Boron

Environment factors not influenced by risk management

Dilution Factor (River) 10

Other given operational conditions affecting environmental exposure

Number of emission days per year 365
Emission or Release Factor: Water 100 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent 2.000 m3/d

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Percentage removed from waste 0 %
water

Remarks The concentration in the sewage treatment plant should be below the respective PNEC STP

Conditions and measures related to external treatment of waste for disposal

Disposal methods Dispose of as hazardous waste in compliance with local and national regulations.

Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice Sweep up or vacuum up spillage and collect in suitable container for disposal.

3. Exposure estimation and reference to its source

Environment

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC8a, ERC8d		Fresh water	0,35	EUSES
			Sewage treatment plant	0,96	EUSES

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).

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

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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 environmental exposure assessments, please refer to the ARCHE tool at www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool.