

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 15.09.2019

Version 1.5

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

Catalogue No.	100156
Product name	Boric acid cryst., EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF
REACH Registration Number	01-2119486683-25-XXXX
CAS-No.	10043-35-3

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

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

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

1.4 Emergency telephone number **Please contact the regional company representation in your country.****SECTION 2. Hazards identification****2.1 Classification of the substance or mixture**
Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B, H360FD

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*

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Product name Boric acid cryst., EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF

Danger

Hazard statements

H360FD May damage fertility. May damage the unborn child.

Precautionary statements

Prevention

P201 Obtain special instructions before use.

Response

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

Restricted to professional users.

Index-No. 005-007-00-2

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	H ₃ BO ₃	BH ₃ O ₃ (Hill)
Index-No.	005-007-00-2	
EC-No.	233-139-2	
Molar mass	61,83 g/mol	

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

Chemical name (Concentration)

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

PBT/vPvB: Not applicable for inorganic substances

10043-35-3	01-2119486683-25-XXXX	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.

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. Remove contact lenses.

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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

drop in temperature, agitation, spasms, Diarrhoea, Nausea, Vomiting, Tiredness, ataxia (impaired locomotor coordination)

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.

Fire may cause evolution of:

boron compounds

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.

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

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6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Observe label precautions.

Work under hood. Do not inhale substance/mixture.

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.

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

Derived No Effect Level (DNEL)

Worker DNEL, longterm	Systemic effects	inhalation	8,3 mg/m ³
Worker DNEL, longterm	Systemic effects	dermal	392 mg/kg Body weight
Consumer DNEL, longterm	Systemic effects	inhalation	4,15 mg/m ³
Consumer DNEL, longterm	Systemic effects	dermal	196 mg/kg Body weight
Consumer DNEL, longterm	Systemic effects	oral	0,98 mg/kg Body weight
Consumer DNEL, acute	Systemic effects	oral	0,98 mg/kg Body weight

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	2,02 mg/l
PNEC Marine water	2,02 mg/l
PNEC Aquatic intermittent release	13,7 mg/l
PNEC Sewage treatment plant	10 mg/l
PNEC Soil	5,4 mg/kg

8.2 Exposure controls

Engineering measures

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

See section 7.1.

Individual protection measures

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

Eye/face protection

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

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

Environmental exposure controls

Do not let product enter drains.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

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Form	solid
Colour	white
Odour	odourless
Odour Threshold	Not applicable
pH	3,8 - 4,8 at 33 g/l 20 °C
Melting point	Not applicable, (decomposition)
Boiling point	No information available.
Flash point	Not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	The product is not flammable. Flammability (solids)
Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapour pressure	< 1 Pa at 25 °C Method: OECD Test Guideline 104
Relative vapour density	No information available.
Density	1,489 g/cm ³ at 23 °C Method: OECD Test Guideline 109
Relative density	No information available.
Water solubility	49,2 g/l at 20 °C Method: OECD Test Guideline 105
Partition coefficient: n-octanol/water	log Pow: -1,09 (22 °C) OECD Test Guideline 107 Bioaccumulation is not expected.
Auto-ignition temperature	No information available.
Decomposition temperature	70 °C

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Viscosity, dynamic No information available.
Explosive properties Not classified as explosive.
Oxidizing properties none

9.2 Other data

Ignition temperature not combustible
Bulk density ca.400 - 600 kg/m³

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

hygroscopic

10.3 Possibility of hazardous reactions

Risk of explosion with:

Acetic anhydride

Violent reactions possible with:

strong oxidising agents, Bases

10.4 Conditions to avoid

no information available

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: 3.450 - 4.080 mg/kg

(ECHA)

Acute inhalation toxicity

LC50 Rat: > 2,03 mg/l; 4 h ; dust/mist

OECD Test Guideline 403

(highest concentration to be prepared)

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Acute dermal toxicity

LD50 Rabbit: > 2.000 mg/kg
(ECHA)

Skin irritation

Rabbit
Result: No skin irritation

(ECHA)

Eye irritation

Rabbit
Result: slight irritation
OECD Test Guideline 405

Sensitisation

Buehler Test Guinea pig
Result: negative
Method: OECD Test Guideline 406

Germ cell mutagenicity

Genotoxicity in vivo

In vivo micronucleus test
Mouse
male and female
oral
Result: negative
Method: OECD Test Guideline 474

Genotoxicity in vitro

Ames test
Salmonella typhimurium
Result: negative
Method: OECD Test Guideline 471

Mutagenicity (mammal cell test):
Mouse lymphoma test
Result: negative
Method: OECD Test Guideline 476

Mutagenicity (mammal cell test):
Chinese hamster ovary cells
Result: negative
Method: OECD Test Guideline 482

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

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CMR effects

Reproductive toxicity:

May damage fertility. May damage the unborn child.

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

After absorption of large quantities:

Vomiting, Nausea, Diarrhoea, agitation, spasms, Tiredness, ataxia (impaired locomotor coordination), drop in temperature

Other dangerous properties can not be excluded.

This substance should be handled with particular care.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

flow-through test LC50 *Oncorhynchus mykiss* (rainbow trout): 79 mg/l; 96 h
(ECOTOX Database)

Toxicity to daphnia and other aquatic invertebrates

static test EC50 *Daphnia magna* (Water flea): 133 mg/l; 48 h
(ECOTOX Database)

Toxicity to algae

static test EC50 *Pseudokirchneriella subcapitata* (green algae): 52,4 mg/l; 74,5 h

Analytical monitoring: yes

OECD Test Guideline 201

Toxicity to fish (Chronic toxicity)

semi-static test NOEC *Danio rerio* (zebra fish): 6,4 mg/l; 34 d

OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

semi-static test NOEC *Daphnia magna* (Water flea): 34,2 mg/l; 21 d

OECD Test Guideline 211

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

log Pow: -1,09 (22 °C)

OECD Test Guideline 107

Bioaccumulation is not expected.

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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

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)

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 Legislation	SEVESO III 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 not regulated that deplete the ozone layer

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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

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: boric acid

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.

H360FD May damage fertility. May damage the unborn child.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Danger

Hazard statements

H360 May damage fertility or the unborn child.

Precautionary statements

Prevention

P201 Obtain special instructions before use.

Response

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

Further information

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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

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

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

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EXPOSURE SCENARIO 1 (Industrial use)

1. Industrial use Pharmaceutical production)

Sectors of end-use

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

Chemical product category

PC19 Intermediate

Process categories

PROC1 Use in closed process, no likelihood of exposure
PROC2 Use in closed, continuous process with occasional controlled exposure
PROC3 Use in closed batch process (synthesis or formulation)
PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact)
PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC15 Use as laboratory reagent
PROC26 Handling of solid inorganic substances at ambient temperature

Environmental Release Categories

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

2. Contributing scenarios: Operational conditions and risk management measures 2.1 Contributing scenario controlling environmental exposure for: ERC1

Amount used

Annual amount per site 55000 t
Remarks Expressed as, Boron

Environment factors not influenced by risk management

Dilution Factor (River) 37

Other given operational conditions affecting environmental exposure

Number of emission days per year 220
Emission or Release Factor: Air 0,53 g/t
Emission or Release Factor: 554 g/t

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Water

Technical conditions and measures / Organizational measures

Air exhaust air scrubber
Fabric filter
Air cyclones for dust collection
Electrostatic precipitation for dust collection.

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant not required
Type of Sewage Treatment Plant Municipal sewage treatment plant
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.

2.2 Contributing scenario controlling environmental exposure for: ERC2

Amount used

Annual amount per site 950 kg
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 200
Emission or Release Factor: Air 400 g/t
Emission or Release Factor: Water 8000 g/t

Technical conditions and measures / Organizational measures

Air exhaust air scrubber
Fabric filter
Air cyclones for dust collection
Electrostatic precipitation for dust collection.

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant not required
Type of Sewage Treatment Plant Municipal sewage treatment plant

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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.

2.3 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

Other given operational conditions affecting environmental exposure

Number of emission days per year 365
Emission or Release Factor: 36562 g/t
Air
Emission or Release Factor: 1
Water

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant not required
Type of Sewage Treatment Plant Municipal sewage treatment plant
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.

2.4 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 300
Emission or Release Factor: Air 36562 g/t
Emission or Release Factor: Water 60000 g/t

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant not required
Type of Sewage Treatment Plant Municipal sewage treatment plant
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.

2.5 Contributing scenario controlling worker exposure for: PROC1, PROC3

Product characteristics

Concentration of the Substance in Mixture/Article Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) Solid, high dustiness, powder

Frequency and duration of use

Frequency of use 8 hours/day

Other operational conditions affecting workers exposure

Outdoor / Indoor Indoor
Remarks Industrial use, Direct handling, Non-dispersive use, Intermittent contact

Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours.

2.6 Contributing scenario controlling worker exposure for: PROC2

Product characteristics

Concentration of the Substance in Mixture/Article Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) Solid, high dustiness, powder

Frequency and duration of use

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Frequency of use 60 minutes/day

Other operational conditions affecting workers exposure

Outdoor / Indoor Indoor with local exhaust ventilation (LEV)
Remarks Non-dispersive use, Direct handling, Intermittent contact, Integrated local exhaust ventilation

Technical conditions and measures

Use only in area provided with appropriate exhaust ventilation. Provide extraction ventilation at points where emissions occur. Provide extract ventilation to material transfer points and other openings.

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid carrying out operation for more than 1 hour. Regular testing and maintenance of plant and equipment

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

In case of insufficient local exhaust ventilation, respiratory protection must be worn

Wear suitable gloves (tested to EN374), coverall and eye protection.

2.7 Contributing scenario controlling worker exposure for: PROC4, PROC5

Product characteristics

Concentration of the Substance in Mixture/Article Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) Solid, high dustiness, powder

Frequency and duration of use

Frequency of use 8 hours/day

Other operational conditions affecting workers exposure

Outdoor / Indoor Indoor with local exhaust ventilation (LEV)
Remarks Industrial use, Direct handling, Non-dispersive use, Intermittent contact, Integrated local exhaust ventilation

Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours.

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

Wear respiratory protection. Effectiveness (of a measure): 90 %

2.8 Contributing scenario controlling worker exposure for: PROC9

Product characteristics

Concentration of the Substance in Mixture/Article Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) Solid, high dustiness

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Physical Form (at time of use) Liquid mixture, paste

Frequency and duration of use

Frequency of use 8 hours/day

Other operational conditions affecting workers exposure

Outdoor / Indoor Indoor with local exhaust ventilation (LEV)
Remarks Industrial use, Non-dispersive use, Direct handling,
Intermittent contact, Integrated local exhaust
ventilation

Technical conditions and measures

Use only in area provided with appropriate exhaust ventilation. Provide extraction ventilation at points where emissions occur. Provide extract ventilation to material transfer points and other openings.

Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours. Regular testing and maintenance of plant and equipment

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

Wear suitable gloves (tested to EN374), coverall and eye protection.

Safety shoes

Suitable mask with particle filter P3 (European Norm 143)

2.9 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 % (unless stated differently).
Physical Form (at time of use) Solid, high dustiness, powder

Frequency and duration of use

Frequency of use 60 minutes/day

Other operational conditions affecting workers exposure

Remarks Non-dispersive use, Non-direct handling, Incidental contact

Technical conditions and measures

Handle in a fume cupboard or under extract ventilation.

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid carrying out operation for more than 1 hour. Regular testing and maintenance of plant and equipment

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

Safety glasses

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Lab coat

Safety shoes

Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice Wear suitable gloves tested to EN374.

2.10 Contributing scenario controlling worker exposure for: PROC26

Product characteristics

Concentration of the Substance in Mixture/Article Covers the percentage of the substance in the product up to 100 % (unless stated differently).
Physical Form (at time of use) Solid, high dustiness, powder

Frequency and duration of use

Frequency of use < 4 hours/day

Other operational conditions affecting workers exposure

Outdoor / Indoor Indoor with local exhaust ventilation (LEV)
Remarks Industrial use, Direct handling, Non-dispersive use, Intermittent contact, Integrated local exhaust ventilation

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid carrying out operation for more than 4 hours.

3. Exposure estimation and reference to its source

Environment

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC1		Fresh water	0,954	EUSES
			Soil	0,002	EUSES
2.2	ERC2		Fresh water	0,969	EUSES
			Soil	0,01	EUSES
2.3	ERC4		Fresh water	0,977	EUSES
			Soil	0,013	EUSES
2.4	ERC6a, ERC6b		Fresh water	0,969	EUSES
			Soil	0,158	EUSES

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Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.5	PROC1	longterm, inhalative, systemic	0,007	MEASE
		longterm, combined, systemic	< 0,001	MEASE
		longterm, dermal, systemic	0,007	
2.5	PROC3	longterm, inhalative, systemic	0,690	MEASE
		longterm, dermal, systemic	< 0,001	MEASE
		longterm, combined, systemic	0,690	
2.6	PROC2	longterm, inhalative, systemic	0,33	MEASE
		longterm, dermal, systemic	< 0,001	MEASE
		longterm, combined, systemic	0,33	
2.7	PROC4	longterm, inhalative, systemic	0,276	MEASE
		longterm, combined, systemic	< 0,001	MEASE
		longterm, dermal, systemic	0,276	
2.7	PROC5	longterm, inhalative, systemic	0,276	MEASE
		longterm, dermal, systemic	< 0,001	MEASE
		longterm, combined, systemic	0,276	
2.8	PROC9	longterm, inhalative, systemic	0,276	Measured data
		longterm, dermal, systemic	< 0,001	MEASE
		longterm, combined, systemic	0,276	
2.9	PROC15	longterm, inhalative, systemic	0,110	Measured data
		longterm, dermal, systemic	< 0,001	MEASE
		longterm, combined, systemic	0,110	
2.10	PROC26	longterm, inhalative, systemic	0,662	MEASE
		longterm, combined, systemic	< 0,001	MEASE
		longterm, dermal, systemic	0,662	

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Catalogue No. 100156
Product name Boric acid cryst., 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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