



SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Revision Date 04/02/2014

Version 1.2

SECTION 1. Identification

Product identifier

Product number	100160
Product name	Boric acid cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,NF
CAS-No.	10043-35-3

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

Identified uses	Pharmaceutical production, Cosmetic raw material
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Details of the supplier of the safety data sheet

Company	EMD Millipore Corporation 290 Concord Road, Billerica, MA 01821, United States of America General Inquiries: +1-978-751-4321 Monday to Friday, 9:00 AM to 4:00 PM Eastern Time (GMT-5)
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Emergency telephone	800-424-9300 CHEMTREC (USA) +1-703-527-3887 CHEMTREC (International) 24 Hours/day; 7 Days/week
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SECTION 2. Hazards identification

GHS Classification

Reproductive toxicity, Category 1B, H360FD

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

GHS-Labeling

Hazard pictograms



Signal Word

Danger

Hazard Statements

H360FD May damage fertility. May damage the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.

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

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Restricted to professional users.

OSHA Hazards

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200). This information is based on 29 CFR 1910.1200 criteria prior to adoption of the GHS and may deviate from the GHS information.

Other hazards

None known.

SECTION 3. Composition/information on ingredients

Formula	H ₃ BO ₃	BH ₃ O ₃ (Hill)
Molar mass	61.83 g/mol	

Hazardous ingredients

Chemical Name (Concentration)

CAS-No.

Boric acid (>= 90 % - <= 100 %)

10043-35-3

Exact percentages are being withheld as a trade secret.

SECTION 4. First aid measures

Description of first-aid measures

Inhalation

After inhalation: fresh air. Call in physician.

Skin contact

After skin contact: wash off with plenty of water. Remove contaminated clothing. Consult a physician.

Eye contact

After eye contact: rinse out with plenty of water with the eyelid held wide open. Call in ophthalmologist if necessary.

Ingestion

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

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

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

Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Fire-fighting measures

Extinguishing media

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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.

Special hazards arising from the substance or mixture

Not combustible.

Advice for firefighters

Special protective equipment for fire-fighters

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

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.

Environmental precautions

Do not empty into drains.

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.

SECTION 7. Handling and storage

Precautions for safe handling

Observe label precautions.

Work under hood. Do not inhale substance/mixture.

Conditions for safe storage, including any incompatibilities

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

Storage temperature: no restrictions.

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SECTION 8. Exposure controls/personal protection

Exposure limit(s)

Ingredients

Basis	Value	Threshold limits	Remarks
<i>Boric acid 10043-35-3</i>			
ACGIH	Time Weighted Average (TWA):	2 mg/m ³	Form of exposure: Inhalable fraction.
	Short Term Exposure Limit (STEL):	6 mg/m ³	Form of exposure: Inhalable fraction.

Engineering measures

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

Individual protection measures

Protective clothing should be selected specifically for the workplace, depending on concentration and quantity of the hazardous substances handled. The chemical resistance of the protective equipment should be inquired at the respective supplier.

Hygiene measures

Immediately change contaminated clothing. Apply skin- protective barrier cream. Wash hands and face after working with substance.

Eye/face protection

Safety glasses

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Other protective equipment:

protective clothing

Respiratory protection

required when dusts are generated.

Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

SECTION 9. Physical and chemical properties

Physical state	solid
Color	white
Odor	odorless
Odor Threshold	No information available.

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pH	3.8 - 4.8 at 33 g/l 68 °F (20 °C)
Melting point	185 °C (decomposition)
Boiling point	No information available.
Flash point	does not flash
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Vapor pressure	2.7 hPa at 68 °F (20 °C)
Relative vapor density	No information available.
Density	1.44 g/cm ³ at 68 °F (20 °C)
Relative density	No information available.
Water solubility	50 g/l at 70 °F (21 °C)
Partition coefficient: n-octanol/water	log Pow: 0.757 (25 °C) (experimental) (IUCLID) Bioaccumulation is not expected.
Autoignition temperature	No information available.
Decomposition temperature	364.8 °F (184.9 °C)
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none
Ignition temperature	not combustible
Bulk density	ca.400 - 600 kg/m ³

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SECTION 10. Stability and reactivity

Reactivity

See below

Chemical stability

hygroscopic

Possibility of hazardous reactions

Exothermic reaction with:

Risk of explosion with:

Acetic anhydride

Conditions to avoid

no information available

Incompatible materials

no information available

Hazardous decomposition products

no information available

SECTION 11. Toxicological information

Information on toxicological effects

Likely route of exposure

Eye contact, Skin contact, Ingestion

Acute oral toxicity

LD50 rat: 2,660 mg/kg (RTECS)

Symptoms: Nausea, Vomiting, Diarrhea

Acute inhalation toxicity

LC50 rat: > 2.03 mg/l

OECD Test Guideline 403

Acute dermal toxicity

LD50 rat: > 2,000 mg/kg

(IUCLID)

Skin irritation

rabbit

Result: slight irritation

(IUCLID)

Eye irritation

rabbit

Result: slight irritation

(IUCLID)

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Sensitization

Sensitization test: guinea pig

Result: negative

Method: OECD Test Guideline 406

Genotoxicity in vitro

Mutagenicity (mammal cell test): chromosome aberration.

Result: negative

(National Toxicology Program)

Ames test

Result: negative

(IUCLID)

CMR effects

Teratogenicity:

May damage the unborn child.

Reproductive toxicity:

May damage fertility.

Specific target organ systemic toxicity - single exposure

The substance or mixture is not classified as specific target organ toxicant, single exposure.

Specific target organ systemic toxicity - repeated exposure

The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration hazard

Regarding the available data the classification criteria are not fulfilled.

Carcinogenicity

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

ACGIH

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

Further information

After absorption of large quantities:

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

Further data:

Handle in accordance with good industrial hygiene and safety practice.

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SECTION 12. Ecological information

Ecotoxicity

Toxicity to fish

LC50 Oncorhynchus mykiss (rainbow trout): 50 - 100 mg/l; 96 h (ECOTOX Database)

Toxicity to daphnia and other aquatic invertebrates

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

Persistence and degradability

Biodegradability

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

Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: 0.757 (25 °C)

(experimental)

(IUCLID) Bioaccumulation is not expected.

Mobility in soil

No information available.

Additional ecological information

Discharge into the environment must be avoided.

SECTION 13. Disposal considerations

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

SECTION 14. Transport information

Land transport (DOT)

Not classified as dangerous in the meaning of transport regulations.

Air transport (IATA)

Not classified as dangerous in the meaning of transport regulations.

Sea transport (IMDG)

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. Regulatory information

United States of America

OSHA Hazards

Teratogen

Reproductive hazard

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SARA 311/312 Hazards

Chronic Health Hazard

SARA 313

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 302

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

DEA List I

Not listed

DEA List II

Not listed

US State Regulations

Massachusetts Right To Know

Remarks

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Ingredients

Boric acid

New Jersey Right To Know

Ingredients

Boric acid

California Prop 65 Components

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

Notification status

TSCA: All components of the product are listed in the TSCA-inventory.

DSL: All components of this product are on the Canadian DSL.

SECTION 16. Other information

Training advice

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Provide adequate information, instruction and training for operators.

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

H360FD

May damage fertility. May damage the unborn child.

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.

Revision Date 04/02/2014

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to appropriate safety precautions. It does not represent a warranty of any product properties and we assume no liability for any loss or injury which may result from the use of this information. Users should conduct their own investigations to determine the suitability of the information.

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