



SAFETY DATA SHEET

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

Revision Date 10/23/2015

Version 1.3

SECTION 1. Identification

Product identifier

Product number	108386
Product name	Tris(hydroxymethyl)aminomethane (Trometamol) suitable for use as excipient EMPROVE® exp Ph Eur,BP,JPC,USP
CAS-No.	77-86-1

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: +1-978-715-4321 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-Labeling

Not a dangerous substance according to GHS.

Other hazards

None known.

SECTION 3. Composition/information on ingredients

Formula	$H_2NC(CH_2OH)_3$	$C_4H_{11}NO_3$ (Hill)
Molar mass	121.14 g/mol	

Remarks	No hazardous ingredients according to the OSHA Hazard Communication Standard 29 CFR 1910.1200.
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SECTION 4. First aid measures

Description of first-aid measures

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Inhalation

After inhalation: fresh air.

Skin contact

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

Eye contact

After eye contact: rinse out with plenty of water.

Ingestion

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Nausea, Vomiting, Convulsions, Diarrhea

The following applies to aliphatic amines in general: irritations after contact with eyes and skin.

Mucosal irritations, coughing, and dyspnoea after inhalation.

Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Fire-fighting measures

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.

Special hazards arising from the substance or mixture

Combustible.

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

Fire may cause evolution of:

nitrogen oxides

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

Advice for firefighters

Special protective equipment for fire-fighters

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

Further information

Suppress (knock down) gases/vapors/mists with a water spray jet. 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. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders:

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Protective equipment see section 8.

Environmental precautions

Do not let product enter 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.

Conditions for safe storage, including any incompatibilities

Tightly closed. Dry.

Store at +15°C to +25°C (+59°F to +77°F).

SECTION 8. Exposure controls/personal protection

Exposure limit(s)

Contains no substances with occupational exposure limit values.

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

Change contaminated clothing. Wash hands 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.

Respiratory protection

required when dusts are generated.

Recommended Filter type: Filter P 1 (acc. to DIN 3181) for solid particles of inert substances

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are performed according to the instructions of the producer. These measures have to be properly documented.

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SECTION 9. Physical and chemical properties

Physical state	solid
Color	white
Odor	odorless
Odor Threshold	Not applicable
pH	10.2 - 10.6 at 6 g/l 20 °C (20 °C)
Melting point	168 - 172 °C
Boiling point/boiling range	219 - 220 °C (219 - 220 °C) at 13.3 hPa
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.
Vapor pressure	0.000267 Pa at 20 °C (20 °C)
Relative vapor density	No information available.
Density	1.353 g/cm ³ at 23 °C (23 °C)
Relative density	No information available.
Water solubility	800 g/l at 20 °C (20 °C)
Partition coefficient: n-octanol/water	log Pow: -2.31 (20 °C) OECD Test Guideline 107 Bioaccumulation is not expected.
Autoignition temperature	No information available.
Decomposition temperature	No information available.

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Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none
Bulk density	ca.840 kg/m ³

SECTION 10. Stability and reactivity

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.

Chemical stability

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

Possibility of hazardous reactions

Violent reactions possible with:

Oxidizing agents, Bases

Caution! In contact with nitrites, nitrates, nitrous acid possible liberation of nitrosamines!

Conditions to avoid

no information available

Incompatible materials

no information available

Hazardous decomposition products

in the event of fire: See section 5.

SECTION 11. Toxicological information

Information on toxicological effects

Likely route of exposure

Eye contact, Skin contact, Ingestion

Acute oral toxicity

LD50 Rat: > 5,000 mg/kg

OECD Test Guideline 425

Acute dermal toxicity

LD50 Rat: > 5,000 mg/kg

OECD Test Guideline 402

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Skin irritation

Rabbit

Result: No skin irritation

OECD Test Guideline 404

Eye irritation

Rabbit

Result: No eye irritation

OECD Test Guideline 405

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 swallowing of large amounts:

Diarrhea, Nausea, Vomiting, Convulsions

The following applies to aliphatic amines in general: irritations after contact with eyes and skin.

Mucosal irritations, coughing, and dyspnoea after inhalation., This substance should be handled with particular care.

Under given conditions, contact with nitrites or nitric acid can lead to the formation of nitrosamines, which have shown themselves to be carcinogenic in animal experiments.

However, when the product is handled appropriately, hazardous effects are unlikely to occur.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

Ecotoxicity

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Toxicity to fish

LC50 *Leuciscus idus* (Golden orfe): 460 mg/l; 96 h
OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates

EC50 *Daphnia magna* (Water flea): > 980 mg/l; 48 h
OECD Test Guideline 202

Toxicity to algae

ErC50 *Pseudokirchneriella subcapitata* (green algae): 397 mg/l; 72 h
OECD Test Guideline 201

Toxicity to bacteria

EC50 activated sludge: > 1,000 mg/l; 3 h
OECD Test Guideline 209

Persistence and degradability

Biodegradability

89 %; 28 d
OECD Test Guideline 301D
Readily biodegradable.

Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: -2.31 (20 °C)
OECD Test Guideline 107
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.

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SECTION 15. Regulatory information

United States of America

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

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.

US State Regulations

Massachusetts Right To Know

Remarks

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

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

Provide adequate information, instruction and training for operators.

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 10/23/2015

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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