

SAFETY DATA SHEET

Version 8.2
Revision Date 03/01/2021
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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifiers**

Product name : Tris(Hydroxymethyl)aminomethane
(Trometamol) high purity EMPROVE® EXPERT
Ph Eur,BP,ChP,JPC,USP,ACS

Product Number : 1.08307
Catalogue No. : 108307
Brand : Millipore
CAS-No. : 77-86-1

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

Identified uses : Pharmaceutical production

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Inc.
3050 SPRUCE ST
ST. LOUIS MO 63103
UNITED STATES

Telephone : +1 314 771-5765
Fax : +1 800 325-5052

1.4 Emergency telephone

Emergency Phone # : 800-424-9300 CHEMTREC (USA) +1-703-
527-3887 CHEMTREC (International) 24
Hours/day; 7 Days/week

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

Not a hazardous substance or mixture.

2.2 GHS Label elements, including precautionary statements

Not a hazardous substance or mixture.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none**SECTION 3: Composition/information on ingredients****3.1 Substances**

Formula : C₄H₁₁N₃O₃

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Molecular weight : 121.14 g/mol
CAS-No. : 77-86-1
EC-No. : 201-064-4

No components need to be disclosed according to the applicable regulations.

SECTION 4: First aid measures

4.1 Description of first-aid measures

If inhaled

After inhalation: fresh air.

In case of skin contact

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

In case of eye contact

After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed

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

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO₂) Dry powder

Unsuitable extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Nitrogen oxides (NO_x)

Combustible.

Fire may cause evolution of:

nitrogen oxides

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

5.3 Advice for firefighters

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

5.4 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

6.1 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.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

Recommended storage temperature see product label.

Storage class (TRGS 510): 11: Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

Change contaminated clothing. Wash hands after working with substance.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

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).

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested: KCL 741 Dermatrill® L

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).

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested: KCL 741 Dermatrill® L

Respiratory protection

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | |
|---|--|
| a) Appearance | Form: solid
Color: white |
| b) Odor | slight, characteristic |
| c) Odor Threshold | No data available |
| d) pH | 10.2 - 10.6 at 6 g/l at 20 °C (68 °F) |
| e) Melting point/freezing point | Melting point/range: 169 °C (336 °F) at ca. 1,013 hPa - OECD Test Guideline 102 |
| f) Initial boiling point and boiling range | 288 °C 550 °F at 1,013 hPa - OECD Test Guideline 103 - Decomposition at boiling point. |
| g) Flash point | () Not applicable |
| h) Evaporation rate | No data available |
| i) Flammability (solid, gas) | No data available |
| j) Upper/lower flammability or explosive limits | No data available |
| k) Vapor pressure | < 0.1 hPa at 20 °C (68 °F) |
| l) Vapor density | No data available |
| m) Relative density | 1.32 at 20.4 °C (68.7 °F) - OECD Test Guideline 109 |

n) Water solubility	678 g/l at 20 °C (68 °F) - completely soluble
o) Partition coefficient: n-octanol/water	log Pow: -2.31 at 20 °C (68 °F) - Bioaccumulation is not expected.
p) Autoignition temperature	The substance or mixture is not classified as self heating.
q) Decomposition temperature	143 °C (289 °F) -
r) Viscosity	Not applicable
s) Explosive properties	No data available
t) Oxidizing properties	No data available

9.2 Other safety information

Bulk density	ca.840 kg/m ³
Solubility in other solvents	ethyl acetate at 20 °C (68 °F) - slightly soluble Alcohol at 20 °C (68 °F) - soluble Dimethylformamide at 20 °C (68 °F) - soluble Acetone at 20 °C (68 °F) - soluble Chloroform at 20 °C (68 °F) - practically insoluble
Dissociation constant	8.22 at 25 °C (77 °F)

SECTION 10: Stability and reactivity

10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Violent reactions possible with:

Oxidizing agents

Bases

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

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - female - > 5,000 mg/kg
(OECD Test Guideline 425)

Inhalation: No data available

LD50 Dermal - Rat - male and female - > 5,000 mg/kg
(OECD Test Guideline 402)

No data available

Skin corrosion/irritation

Skin - Rabbit

Result: No skin irritation - 4 h
(OECD Test Guideline 404)

Serious eye damage/eye irritation

Eyes - Rabbit

Result: No eye irritation
(OECD Test Guideline 405)

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Mutagenicity (mammal cell test): chromosome aberration.

Chinese hamster lung cells

Result: negative

In vitro mammalian cell gene mutation test

Chinese hamster ovary cells

Result: negative

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.

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.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Additional Information

Repeated dose toxicity - Rat - male and female - Oral - 90 d - NOAEL (No observed adverse effect level) - 250 mg/kg - LOAEL (Lowest observed adverse effect level) - 1,000 mg/kg
Remarks:

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Subchronic toxicity

The value is given in analogy to the following substances:

Repeated dose toxicity - Rabbit - male and female - 28 d - LOAEL (Lowest observed adverse effect level) - 500 mg/kg

Remarks:

Subacute toxicity

Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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

12.1 Toxicity

Toxicity to daphnia and other aquatic invertebrates	static test EC50 - Daphnia magna (Water flea) - > 980 mg/l - 48 h (OECD Test Guideline 202)
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Toxicity to bacteria	static test EC50 - activated sludge - > 1,000 mg/l - 3 h (OECD Test Guideline 209)
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12.2 Persistence and degradability

Biodegradability	aerobic - Exposure time 28 d Result: 97.1 % - Readily biodegradable. (OECD Test Guideline 301F)
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12.3 Bioaccumulative potential

No bioaccumulation is to be expected (log Pow ≤ 4).

12.4 Mobility in soil

No data available

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12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. 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

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

SARA 302 Components

This material does not contain any components with a section 302 EHS TPQ.

SARA 313 Components

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.

Massachusetts Right To Know Components

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

SECTION 16: Other information

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the

present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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