



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 23.05.2014

Version 1.3

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Catalogue No.	108219
Product name	Tris(hydroxymethyl)aminomethane hydrochloride suitable for biopharmaceutical production EMPROVE® bio
REACH Registration Number	A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.
CAS-No.	1185-53-1

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

Identified uses	Pharmaceutical production, Cosmetic raw material For additional information on uses please refer to the Merck Chemicals portal (www.merck-chemicals.com).
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1.3 Details of the supplier of the safety data sheet

Responsible Department	EQ-RS * e-mail: prodsafe@merckgroup.com
Regional representation	Merck Chemicals Ltd * Boulevard Industrial Park * Padge Road * Beeston * Nottingham * NG9 2JR * Tel. 01159 430840 * information@merckchem.co.uk .

1.4 Emergency telephone number	+49 (0) 6151 722440
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SECTION 2. Hazards identification

2.1 Classification of the substance or mixture

This substance is not classified as dangerous according to European Union legislation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	C ₄ H ₁₁ NO ₃ *ClH	C ₄ H ₁₂ ClNO ₃ (Hill)
EC-No.	214-684-5	
Molar mass	157.60 g/mol	

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Catalogue No. 108219
Product name Tris(hydroxymethyl)aminomethane hydrochloride suitable for biopharmaceutical production EMPROVE® bio

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

Remarks No disclosure requirement according to Regulation (EC) No. 1907/2006

3.2 Mixture
not applicable

SECTION 4. First aid measures

4.1 Description of first aid measures

After inhalation: fresh air.

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

After eye contact: rinse out with plenty of water.

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

irritant effects

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

Water, Carbon dioxide (CO₂), Foam, 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

Combustible.

Risk of dust explosion.

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

Fire may cause evolution of:

nitrogen oxides, Hydrogen chloride gas

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.

Suppress (knock down) gases/vapours/mists with a water spray jet.

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.

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Catalogue No. 108219
Product name Tris(hydroxymethyl)aminomethane hydrochloride suitable for biopharmaceutical production EMPROVE® bio

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

Observe label precautions.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

Recommended storage temperature see product label.

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

Contains no substances with occupational exposure limit values.

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.

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

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Catalogue No. 108219
Product name Tris(hydroxymethyl)aminomethane hydrochloride suitable for biopharmaceutical production EMPROVE® bio

splash contact:

Glove thickness:	0.11 mm
Break through time:	> 480 min
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).

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 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	solid
Colour	white
Odour	odourless
Odour Threshold	not applicable
pH	4.2 at 100 g/l 20 °C
Melting point	149 °C
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	May form combustible dust concentrations in air
Lower explosion limit	No information available.

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Catalogue No. 108219
Product name Tris(hydroxymethyl)aminomethane hydrochloride suitable for biopharmaceutical production EMPROVE® bio

Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Density	No information available.
Relative density	No information available.
Water solubility	soluble
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	ca.230 °C
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

none

SECTION 10. Stability and reactivity

10.1 Reactivity

Risk of dust explosion.

10.2 Chemical stability

hygroscopic

10.3 Possibility of hazardous reactions

Violent reactions possible with:

Strong oxidizing agents

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

no information 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 oral toxicity

This information is not available.

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Catalogue No. 108219
Product name Tris(hydroxymethyl)aminomethane hydrochloride suitable for biopharmaceutical production EMPROVE® bio

Acute inhalation toxicity

This information is not available.

Acute dermal toxicity

This information is not available.

Skin irritation

This information is not available.

Eye irritation

Possible damages: slight irritation

Sensitisation

Sensitisation test (Magnusson and Kligman):

Result: negative

Method: OECD Test Guideline 406

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

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

Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia magna (Water flea): > 100 mg/l; 48 h

OECD Test Guideline 202

Toxicity to bacteria

EC50 activated sludge: > 1,000 mg/l; 3 h

OECD Test Guideline 209

12.2 Persistence and degradability

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Catalogue No. 108219
Product name Tris(hydroxymethyl)aminomethane hydrochloride suitable for biopharmaceutical production EMPROVE® bio

Biodegradability

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

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

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

Waste treatment methods

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other 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

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 96/82/EC
Legislation Directive 96/82/EC does not apply

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer not regulated

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Catalogue No. 108219
Product name Tris(hydroxymethyl)aminomethane hydrochloride suitable for biopharmaceutical production EMPROVE® bio

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

Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals not regulated

Substances of very high concern (SVHC) This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of ≥ 0.1 % (w/w).

National legislation

Storage class 10 - 13

Dust explosion class St1

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

SECTION 16. Other information

Training advice

Provide adequate information, instruction and training for operators.

Labelling (67/548/EEC or 1999/45/EC)

The product does not need to be labelled in accordance with EC directives or respective national laws.

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.

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.