

MATERIAL SAFETY DATA SHEET

according to 1907/2006/ EC

**Promethazine HCl**

Date of creation: 19.01.2009

Date of review: 15.12.2021

Version: 22

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SECTION 1.: Identification of the substance/mixture and of the company/undertaking:**1.1 Product identifier****1.1.1 Identification of the substance/
mixture****Promethazine HCl****Synonyms****10H-Phenothiazine-10-ethanamine, N,N-a-trimethyl, monohydrochloride****1.1.2 CAS Number**

58-33-3

1.1.3 EC Number

200-375-2

1.1.4 REACH registration number

Unknown

**1.2 Relevant identified uses of the
substance or mixture and uses
advised against**Pharmaceutical active substance.
Antivertigo, antiemetic. antihistaminic.**1.3 Details of the supplier of the safety data sheet****Manufacturer's name and
address**Egis Pharmaceuticals PLC.
H-1106 Budapest, Keresztúri út 30-38. Hungary
Tel.: (361) 803-5555; e-mail:reach@egis.huInforming department:Egis Production Directorate Tel.: (361) 803-5582
Emergency information:Egis Occupational Safety, Health and Environmental
Protection Division
Tel.: (361) 803-5902; +36-20-340-8307**Supplier/importer**

Egis Pharmaceuticals PLC.

1.4 Emergency telephone numberHealth Toxicological Information Service
Address: 1096 Budapest, Nagyvárad tér 2., Hungary.
1450 Budapest, P.O. Box: 36., Hungary
Tel: (36-1)-476-6464

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SECTION 2.: Hazards identification:

2.1 Classification of the substance or mixture

2.1.1 Classification of the substance according to Regulation (EC) No. 1272/2008

Hazard classes and categories

Acute Tox. 4 = Acute toxic : Category 4
 Skin Irrit. 2 = Skin irritant : Category 2
 Skin Sens. 1 = Skin sensitiser : Category 1
 Eye Dam. 1 = Serious eye damage (irreversible eye effect) : Category 1
 Lact. = Toxic to reproduction : Additional category (lactation)
 STOT SE 3 = Specific target organ toxic - single exposure : Category 3
 Aquatic Chronic 2 = Hazardous to the aquatic environment - chronic : Category 2

Hazardous (H) statements

H302 - Harmful if swallowed.
 H315 - Causes skin irritation.
 H317 - May cause an allergic skin reaction.
 H318 - Causes serious eye damage.
 H362 - May cause harm to breast-fed children.
 H335 - May cause respiratory irritation.
 H411 - Toxic to aquatic life with long lasting effects.

2.2 Label elements

2.2.1 Labelling of the substance according to Regulation (EC) No. 1272/2008

Identification of the substance/ mixture

Promethazine HCl

Authorization number

None

GHS Label elements



Hazardous (H) statements

Danger

H302 - Harmful if swallowed.
 H315 - Causes skin irritation.
 H317 - May cause an allergic skin reaction.
 H318 - Causes serious eye damage.
 H362 - May cause harm to breast-fed children.
 H335 - May cause respiratory irritation.
 H411 - Toxic to aquatic life with long lasting effects.

Precautionary (P) statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.
 P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
 P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing
 P312 - Call a POISON CENTER/doctor if you feel unwell.
 P273 - Avoid release to the environment.

Supplemental hazard information (EUH statements)

None

2.3 Other hazards

Pharmaceutical active substance. Therapeutic category: antihistaminic.

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SECTION 3.: Composition/information on ingredients

3.1 Substances

3.1.1 Identification of the main constituent

The name of the main constituent	Promethazine HCl
Synonyms	10H-Phenothiazine-10-ethanamine, N,N-a-trimethyl, monohydrochloride
CAS Number	58-33-3

3.1.2 Classified impurities and additives relevant for labelling

3.2 Mixtures

SECTION 4.: First-aid measures

4.1 Description of first aid measures

General information	Remove from exposure. Remove contaminated clothing and shoes. Consult a doctor if irritation develop or persist.
After inhalation	Remove to fresh air and monitor breathing. If breathing becoming difficult, give oxygen and consult a physician. If breathing stops, give artificial respiration and consult a physician.
After skin contact	Take off contaminated clothing immediately, wash the skin with plenty of water and soap without any delay. If allergic reaction occurs ask medical advice immediately.
After eye contact	May cause serious damage to eyes! Rinse the eyes with water for at least 20 minutes with eyelids open wide. Obtain medical, ophthalmologic attention immediately.
After swallowing	Wash out the mouth with clear water if the patient is conscious. Consult with a physician.

4.2 Most important symptoms and effects, both acute and delayed

CNS depression and/or stimulation: drowsiness, sedation, coma, excitement, disorientation, hallucinations; dry mouth, occasional blurred vision, blood pressure effects, tachycardia, rash, nausea, vomiting.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.
No specific antidote.

SECTION 5.: Firefighting measures

5.1 Extinguishing media

5.1.1 Suitable extinguishing media:	Water spray, carbon dioxide, extinguishing powder, foam.
5.1.2 Unsuitable extinguishing media:	Unknown

5.2 Special hazards arising from the substance or mixture

CO, CO₂, HCl, SO_x, NO_x

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective clothing for fire-fighting.

5.3.1 Fire hazard class

Extremely flammable solid or danger of explosion

SECTION 6.: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures	Isolate and evacuate affected area. Avoid all contact with the material.
6.2 Environmental precautions	Hinder substance from entering soil, sewers or living water.
6.3 Methods and material for containment and cleaning up	Clean-up spilled material avoiding raising dust using vacuum. Collect the material in a properly labelled container, show on the label "hazardous waste, for disposal". Dispose the hazardous waste by incineration. Wash spill site thoroughly with water after material pickup is complete. Do not let the material and the contaminated water to sewers, drains, underground or living waters. Collect the water in a suitable container, label the container properly and dispose in a similar way to the material itself.
6.4 Reference to other sections	Wear full protective equipment as given in Section 8.

SECTION 7.: Handling and storage

7.1 Precautions for safe handling	
Handling	As a general rule avoid all contact with the material. Avoid contact with eyes. Avoid generation of dust. Avoid inhalation of dust. Use protective equipment described in Section 8.
Safety measures	Suitable general and local exhaust ventillation is needed.
Fire and explosion protection measures	Combustible material. Dust/air mixture may ignite or explode. Take measures against electrostatic discharges.
7.2 Conditions for safe storage, including any incompatibilities	Storage temperature: below 30 °C
7.3 Specific end use(s)	Pharmaceutical production.

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SECTION 8.: Exposure controls/personal protection

8.1 Control parameters

8.1.1 National occupational exposure limit values

AK	None
CK	None
MK	None
OEL	45 µg/m3
OEB/EHC	OEB category 3

8.1.2 Other occupational exposure limit values

None

8.1.3 Relevant regulations and recommended monitoring procedures

Directive 91/322/EEC (indicative limit values) and its amendments
Directive 98/24/EC (risks related to chemical agents at work) and its amendments

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Suitable general and local exhaust ventilation.
Closed system.

8.2.2 Personal protection equipment

Eye/face protection Tightly fitting, chemical resistant safety goggles or full face mask.

Hand protection Chemical resistant gloves.

Respiratory protection FFP3 dust mask or half mask with suitable filter cartridge
OR
full face mask with suitable filter cartridge in cases where the substance has at least one of the following hazard statements: H341, H351, H361, H362, H311, H314, H317 AND is present at a quantity above 500 g.

Personal protection, general hygienic measures Wash hands with soap and water thoroughly after handling.
Provide equipment for eyes flushing and safety shower.
If the handled quantity is above 500g wear full protective clothing in order to avoid skin contact.

8.2.3 Environmental exposure controls

Disposable 5,6 type overalls recommended (liquid splash and dust protection).
Dust exposure measurement in the workplace air environment.

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SECTION 9.: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	Crystalline powder.
Color	White or almost white.
9.2 Odour	Odourless.
Odour threshold	Unknown
9.3 pH-value (transportation state)	None
9.4 Melting point / melting range	230 - 232 °C
9.5 Initial boiling point and boiling range	Unknown
9.6 Flash point	
Open	None
In room	None
9.7 Evaporation rate	Not applicable.
9.8 Flammability (solid, gas)	Combustible material.
9.9 Upper/lower flammability or explosive limits	
Ignition temperature	535 °C
Lower flammability or explosive limits	25 g/m3
Upper flammability or explosive limits	Unknown
9.10 Vapour pressure	Unknown
9.11 Vapour density	Unknown
9.12 Relative density	1.2133 g/cm3
9.13 Solubility	Very well soluble in water.
In water at 20 C°	160 g/100cm3
In water at 100 C°	Unknown
Solubility in organic solvents	1 g/100 ml acetone
9.14 Partition coefficient (n-octanol/ water)	Unknown
9.15 Auto-ignition temperature	Unknown
9.16 Decomposition temperature	Unknown
9.17 Viscosity	Unknown
9.18 Danger of explosion, dust explosion susceptibility	Electrostatically chargeable material. Dust/air mixture may ignite or explode.
9.19 Oxidizing (combustion-sustaining) properties	Unknown

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SECTION 10.: Stability and reactivity

10.1 Reactivity	Possibility to hazardous reactivity is not expected.
10.2 Chemical stability	Stable at normal temperature and pressure.
10.3 Possibility of hazardous reactions	Unknown
10.4 Conditions to avoid	Store protected from from light, heat, air humidity. Keep container tightly closed.
10.5 Incompatible materials	Avoid contact with strong acids, bases, and strong oxidising materials.
10.6 Hazardous decomposition products	Unknown



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SECTION 11.: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

11.1.1	Acute toxicity	
	LD50 (oral, rat)	400 - 800 mg/kg
	LD50 (dermal, rat)	Unknown
	LC50 (inhalation, rat)	Unknown
	Effects of inhalation	Irritation to mucous membranes and upper respiratory tract.
	Effects of swallowing	Harmful if swallowed. Symptoms: CNS depression and/or stimulation: drowsiness, sedation, coma, excitement, disorientation, hallucinations; dry mouth, occasional blurred vision, blood pressure effects, tachycardia, rash, nausea, vomiting.
11.1.2	Skin corrosion/irritation	Causes slight irritation to skin.
11.1.3	Serious eye damage/irritation	Causes serious damage to eyes.
11.1.4	Respiratory or skin sensitisation	May cause sensitisation by skin contact.
11.1.5	Germ cell mutagenicity	Mutagenic potential was not observed in series of in vitro and in vivo genotoxicity tests.
11.1.6	Carcinogenicity	Signs of carcinogenic effects was not observed in animal studies.
11.1.7	Reproductive toxicity	Evidence of reproductive toxicity was not recorded in animal studies. Avoid exposure during pregnancy and breast-feeding.
11.1.8	STOT-single exposure	Not available.
11.1.9	STOT-repeated exposure	Not available.
11.1.10	Aspiration hazard	Crystalline powder. Aspiration hazard is not possible.
11.1.11	Summary of health effects	Harmful if swallowed. Irritating to eyes, respiratory system and skin. Causes severe eye irritation in contact with eyes, may cause irreversible damage to eyes. May cause hypersensitivity in contact with skin. May be harmful to the unborn child.
11.1.12	Information on likely routes of exposure	Dust inhalation, eye contact.
11.1.13	Symptoms related to the physical, chemical and toxicological characteristics	No other special symptoms. See general symptoms in Section 4.2.
11.1.14	Delayed and immediate effects as well as chronic effects from short and long-term exposure	No data are available.
11.1.15	Interactive effects	Not available.
11.1.16	Additional information (mutagenicity, carcinogenicity, reproductive effects, etc.)	No signs of carcinogenic, mutagenic and reproductive toxic effect was observed in animal studies. May cause harm to breast-fed babies, avoid exposure during breast-feeding.

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SECTION 12.: Ecological information

12.1 Toxicity

LC50 (fish)

Unknown

LC50 (Daphnia Magna)

2.3

LC50 (algae)

Unknown

Environmental toxicity

Very toxic to aquatic organism, may cause long-term adverse effects in the aquatic environment.

12.2 Persistence and degradability

Not readily biodegradable.

Biodegradation 2% / 28 days

12.3 Bioaccumulative potential

Unknown

12.3.1 Partition coefficient (n-octanol/
water)

Unknown

12.3.2 Bioconcentration factor (BCF)

None

12.4 Mobility in soil

Data not available.

12.5 Results of PBT and vPvB
assessment

None

12.6 Other adverse effects

Further data not available.

SECTION 13.: Disposal considerations

13.1 Waste treatment methods

13.1.1 Disposal of the product related
waste

Dispose the solid waste or incinerate in accordance of all state and local regulations. Burn the material in a chemical incinerator equipped with an afterburner and scrubber.

13.1.2 Disposal of contaminated
packaging

Dispose according to the state and local regulations.

13.1.3 Relevant community, national
and regional provisions

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste

Directive 91/689/EEC of hazardous wastes.



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SECTION 14.: Transport information

14.1	UN number or ID number ADR	UN3077 - ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
	UN number or ID number RID, ADN, IMDG	Not relevant.
	UN number or ID number ICAO TI	Not relevant.
14.2	UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Promethazine hydrochloride)
14.3	Transport hazard class(es)	9 - Miscellaneous dangerous substances and articles None None
14.4	Packing group	III
14.5	Environmental hazards	Yes
14.5.1	Marine pollutant	Yes
14.6	Special precautions for user	Transport classification: Hungarian Hazardous Goods Engineering Office Ltd. 05.2017
14.7	Maritime transport in bulk according to IMO instruments	None

SECTION 15.: Regulatory information

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	
15.1.1	Most important Hungarian measures	See the relevant regulations in Hungary on the Hungarian MSDS.
15.1.2	European Union measures	Regulation (EC) No 1907/2006 OF THE European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
15.2	Chemical safety assessment	Not required.

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SECTION 16.: Other information

16.1 Full text of H phrases for components

None

16.2 Hazard classes and categories

Acute Tox. 4 = Acute toxic : Category 4
Skin Irrit. 2 = Skin irritant : Category 2
Skin Sens. 1 = Skin sensitizer : Category 1
Eye Dam. 1 = Serious eye damage (irreversible eye effect) : Category 1
Lact. = Toxic to reproduction : Additional category (lactation)
STOT SE 3 = Specific target organ toxic - single exposure : Category 3
Aquatic Chronic 2 = Hazardous to the aquatic environment - chronic : Category 2

16.3 Hazard of mixture definition

16.4 Literature references

RTECS database.
Micromedex Healthcare database.
Toxicological examinations, EGIS Department of Toxicology.
Fire and static hazard examinations.
Toxicological expert opinion.

16.5 Review of changed information compared to the previous version of the safety data sheet

Section 8

16.6 Other information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not be considered a warranty or quality specification. The above information relates only to the specific substance, mixture and its identified uses designated herein and may not be valid for such substance and mixture used in combination with any other substance or in any process or if the substance is latered or processed, unless specified in the text. In case you have further safety information on the substance, mixture or its uses please inform us as soon as possible.

