

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 4.0 Revision Date 13.03.2010

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GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product name : Promethazine hydrochloride

Product Number : P4651

Brand : Sigma

Company : Sigma-Aldrich (Shanghai) Trading Co., Ltd
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2. HAZARDS IDENTIFICATION**Classification of the substance or mixture**

According to Regulation (EC) No1272/2008

Acute toxicity, Inhalation (Category 4)

Acute toxicity, Oral (Category 3)

Skin irritation (Category 2)

Eye irritation (Category 2)

Skin sensitization (Category 1)

Specific target organ toxicity - single exposure (Category 3)

According to European Directive 67/548/EEC as amended.

Harmful by inhalation and if swallowed. Irritating to eyes, respiratory system and skin. May cause sensitization by skin contact. Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Label elements

Pictogram



Signal word

Danger

Hazard statement(s)

H301

Toxic if swallowed.

H315

Causes skin irritation.

H317

May cause an allergic skin reaction.

H319

Causes serious eye irritation.

H332

Harmful if inhaled.

H335

May cause respiratory irritation.

Precautionary statement(s)

P261

Avoid breathing dust/fume/gas/mist/vapours/spray.

P280

Wear protective gloves.

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Hazard symbol(s)	
Xn	Harmful
N	Dangerous for the environment
R-phrases(s)	
R20/22	Harmful by inhalation and if swallowed.
R36/37/38	Irritating to eyes, respiratory system and skin.
R43	May cause sensitization by skin contact.
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S-phrases(s)	
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37	Wear suitable protective clothing and gloves.
S61	Avoid release to the environment. Refer to special instructions/ Safety data sheets.

Other hazards - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms	: 10-[2-(Dimethylamino)propyl]phenothiazinehydrochloride
Formula	: C ₁₇ H ₂₀ N ₂ S · HCl
Molecular Weight	: 320,88 g/mol

CAS-No.	EC-No.	Index-No.	Classification	Concentration
Promethazine hydrochloride				
58-33-3	200-375-2	-	Acute Tox. 4; Acute Tox. 3; Skin Irrit. 2; Eye Irrit. 2; Skin Sens. 1; STOT SE 3; H301, H315, H317, H319, H332, H335 Xn, N, R20/22 - R36/37/38 - R43 - R51/53	-

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

4. FIRST AID MEASURES

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing give artificial respiration Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for fire-fighters

Wear self contained breathing apparatus for fire fighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Conditions for safe storage

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Air, light, and moisture sensitive. Handle and store under inert gas.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protective equipment

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Handle with gloves.

Eye protection

Face shield and safety glasses

Skin and body protection

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	solid
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Safety data

pH	no data available
Melting point	227 - 230 °C
Boiling point	no data available
Flash point	no data available
Ignition temperature	no data available
Lower explosion limit	no data available

Upper explosion limit no data available

Water solubility no data available

10. STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions.

Conditions to avoid

Air, light, and moisture sensitive.

Materials to avoid

Strong oxidizing agents

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NO_x), Sulphur oxides, Hydrogen chloride gas

11. TOXICOLOGICAL INFORMATION

Acute toxicity

LD50 Oral - mouse - 255 mg/kg

Remarks: Behavioral:Convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration:Other changes.

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitization

May cause sensitization by skin contact.

Germ cell mutagenicity

no data available

Carcinogenicity

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

Reproductive toxicity

Reproductive toxicity - rat - Oral

Effects on Fertility: Other measures of fertility

Developmental Toxicity - rat - Oral

Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus).

Specific target organ toxicity - single exposure

Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure

no data available

Aspiration hazard

no data available

Potential health effects

Inhalation

Harmful if inhaled. Causes respiratory tract irritation.

Ingestion

Harmful if swallowed.

Skin

May be harmful if absorbed through skin. Causes skin irritation.

Eyes

Causes eye irritation.

Signs and Symptoms of Exposure

Blurred vision, Dizziness, Rash, Nausea, Vomiting, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Additional Information

RTECS: SO8225000

12. ECOLOGICAL INFORMATION

Toxicity

Toxicity to daphnia and other aquatic invertebrates. EC50 - Daphnia magna (Water flea) - 1,5 mg/l - 48 h

Persistence and degradability

According to the results of tests of biodegradability this product is not readily biodegradable.

Bioaccumulative potential

no data available

Mobility in soil

no data available

PBT and vPvB assessment

no data available

Other adverse effects

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

13. DISPOSAL CONSIDERATIONS

Product

Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

ADR/RID

UN-Number: 2811 Class: 6.1 Packing group: III
Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Promethazine hydrochloride)

IMDG

UN-Number: 2811 Class: 6.1 Packing group: III EMS-No: F-A, S-A
Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Promethazine hydrochloride)
Marine pollutant: No

IATA

UN-Number: 2811 Class: 6.1 Packing group: III
Proper shipping name: Toxic solid, organic, n.o.s. (Promethazine hydrochloride)

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

16. OTHER INFORMATION

Text of H-code(s) and R-phrase(s) mentioned in Section 3

Acute Tox.	Acute toxicity
Eye Irrit.	Eye irritation
H301	Toxic if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.

Skin Irrit.	Skin irritation
N	Dangerous for the environment
Xn	Harmful
R20/22	Harmful by inhalation and if swallowed.
R36/37/38	Irritating to eyes, respiratory system and skin.
R43	May cause sensitization by skin contact.
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Further information

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