Chemical Book India

Chemical Safety Data Sheet MSDS / SDS					
Promethazine hydrochloride SDS					
Revision Date: 2024-04-25 Revision Number: 1					

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

Product identifier	
Product name:	Promethazine hydrochloride
CAS:	58-33-3

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

 Relevant identified
 For R&D use only. Not for medicinal, household or other use.

 uses:
 uses advised

 uses:
 none

 against:

Company Identification

Company:	Chemicalbook.in
Address:	5 vasavi Layout Basaveswara Nilayam Pragathi Nagar Hyderabad, India -500090
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SECTION 2: Hazards identification

Classification of the substance or mixture

Acute toxicity - Category 4, Oral Skin irritation, Category 2 Skin sensitization, Category 1 Eye irritation, Category 2 Acute toxicity - Category 4, Inhalation Specific target organ toxicity - single exposure, Category 3 Hazardous to the aquatic environment, long-term (Chronic) - Category Chronic 2

GHS label elements, including precautionary statements

Pictogram(s)



Signal word Warning

Hazard statement(s)

H302 Harmful 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 H411 Toxic to aquatic life with long lasting effects

Precautionary statement(s)

Prevention

P264 Wash ... thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P271 Use only outdoors or in a well-ventilated area.
P273 Avoid release to the environment.

Response

P301+P317 IF SWALLOWED: Get medical help.
P330 Rinse mouth.
P302+P352 IF ON SKIN: Wash with plenty of water/...
P321 Specific treatment (see ... on this label).
P332+P317 If skin irritation occurs: Get medical help.

P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P317 If skin irritation or rash occurs: Get medical help.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P317 Get medical help.
P319 Get medical help if you feel unwell.
P391 Collect spillage.

Storage

P403+P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up.

Disposal

P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

Other hazards which do not result in classification

no data available

SECTION 3: Composition/information on ingredients

Substance

Chemical name:	Promethazine hydrochloride
Common names and synonyms:	Promethazine hydrochloride
CAS number:	58-33-3
EC number:	200-375-2
Concentration:	100%

SECTION 4: First aid measures

Description of necessary first-aid measures

If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound include excitement, sleepiness, convulsions and rigidity. Other symptoms include leukopenia, agranulocytosis, drowsiness, confusion and stupor. Acute transitory myopia may occur. Central nervous system effects may also occur. It may cause an increase in blood pressure, mild hypotension, jaundice, extra-pyramidal reactions and photosensitivity. It may also cause dizziness, central nervous system depression, vomiting, local anesthesia, abdominal pain, diarrhea and dryness of the mouth, throat and nose. Symptoms of exposure to this type of compound include muscular weakness, tachycardia, nausea, sedation, tinnitus, lassitude, incoordination, fatigue, blurred vision, diplopia, euphoria, nervousness, insomnia, tremors, loss of appetite, epigastric distress, constipation, cough, urinary retention or frequency, dysuria, palpitation, headache, tightness of the chest, tingling, heaviness and weakness of the hands, allergic dermatitis, fever, hemolytic anemia (rare), fixed and dilated pupils, and flushing. In children, exposure can cause hallucinations, excitement, ataxia, incoordination, athetosis and convulsions. ACUTE/CHRONIC HAZARDS: When heated to decomposition this compound emits toxic fumes of hydrochloric acid, sulfur oxides and nitrogen oxides. (NTP, 1992)

Indication of immediate medical attention and special treatment needed, if necessary

Treatment of phenothiazine overdosage generally involves symptomatic and supportive care. There is no specific antidote for phenothiazine intoxication; however, anticholinergic antiparkinsonian drugs may be useful in controlling extrapyramidal reactions associated with phenothiazine overdosage. Following acute ingestion of the drugs, the stomach should be emptied by gastric lavage and consideration also should be given to repeated doses of activated charcoal. If the patient is comatose, having seizures or a dystonic reaction, or lacks the gag reflex, gastric lavage may be useful even several hours after the drug has been ingested, since GI motility may be greatly reduced following overdosage of phenothiazines. Induction of emesis should generally not be attempted, since a phenothiazine-induced dystonic reaction of the head or neck may result in aspiration of vomitus during emesis.

Administration of a saline cathartic may be beneficial in enhancing evacuation of the drug from the GI tract, especially following ingestion of extended-release preparations (eg, Spansules). Phenothiazine General Statement

SECTION 5: Firefighting measures

Suitable extinguishing media

Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Specific hazards arising from the chemical

Flash point data for this chemical are not available; however, it is probably combustible. (NTP, 1992)

Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

Environmental precautions

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

Methods and materials for containment and cleaning up

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

SECTION 7: Handling and storage

Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

Conditions for safe storage, including any incompatibilities

Promethazine hydrochloride preparations should be protected from light. Promethazine hydrochloride oral solution and tablets should be stored in tight, light-resistant containers at 15-30 and 20-25 deg C, respectively, while the rectal suppositories should be stored in well-closed containers at 2-8 deg C. Freezing of the oral solution should be avoided. Following the date of manufacture, commercially available promethazine preparations have expiration dates of 2-5 years depending on the dosage form and manufacturer.

SECTION 8: Exposure controls/personal protection

Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

Thermal hazards

no data available

SECTION 9: Physical and chemical properties and safety characteristics

Physical state:	PHYSICAL DESCRIPTION: Odorless white to faint yellow crystalline powder. Bitter taste. A 10% solution in water has a pH of 3.5-5.0. (NTP, 1992)
Colour:	Crystals
Odour:	no data available
Melting point/freezing point:	-23°C(lit.)
Boiling point or initial boiling point and boiling range:	82°C/7mmHg(lit.)
Flammability:	no data available
Lower and upper explosion limit/flammability limit:	no data available
Flash point:	84°C(lit.)
Auto-ignition temperature:	no data available
Decomposition temperature:	no data available
pH:	no data available
Kinematic viscosity:	no data available
Solubility:	greater than or equal to 100 mg/mL at 72 $^{\circ}$ F (NTP, 1992)

Partition coefficient n- octanol/water:	log Kow = 4.81
Vapour pressure:	1.03X10-5 mm Hg at 25 deg C (est)
Density and/or relative density:	1.131 g/cm3
Relative vapour density:	no data available
Particle characteristics:	no data available

SECTION 10: Stability and reactivity

Reactivity

Slowly oxidizes in air, acquiring a blue color. Also turns blue on exposure to moisture. Water soluble.

Chemical stability

In general, promethazine HCl exhibits increasing stability with decreasing pH. Promethazine HCl

Possibility of hazardous reactions

PROMETHAZINE HYDROCHLORIDE is sensitive to light. In aqueous solution, it is degraded by heat and light (more rapidly in air or oxygen). Incompatible with alkalis and alkaline solutions such as those of aminophylline, soluble barbiturates and phenytoin sodium. Iron(III) and copper(III) accelerate the degradation (NTP, 1992).

Conditions to avoid

no data available

Incompatible materials

Promethazine hydrochloride injection has been reported to be chemically incompatible with several drugs, especially those with an alkaline pH. However, the compatibility depends on several factors (eg, concentration of the drugs, specific diluents used, resulting pH, temperature).

Hazardous decomposition products

When heated to decomposition it emits very toxic fumes of /nitrogen oxides and sulfur oxides/.

SECTION 11: Toxicological information

Acute toxicity Oral: LD50 Rabbit oral 580 mg/kg Inhalation: no data available Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

SECTION 12: Ecological information

Toxicity

Toxicity to fish: no data available Toxicity to daphnia and other aquatic invertebrates: no data available Toxicity to algae: no data available Toxicity to microorganisms: no data available

Persistence and degradability

no data available

Bioaccumulative potential

no data available

Mobility in soil

The distribution coefficient, Kd, was found to be from 206 to 1,575 L/kg for promethazine in 12 soils and sediments collected in Australia; organic content in soils and sediments ranged from 0.08% to 8.6%(1).

Other adverse effects

no data available

SECTION 13: Disposal considerations

Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

SECTION 14: Transport information

UN Number

ADR/RID: UN3077 (For reference only, please check.) IMDG: UN3077 (For reference only, please check.) IATA: UN3077 (For reference only, please check.)

UN Proper Shipping Name

ADR/RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (For reference only, please check.) IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (For reference only, please check.) IATA: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (For reference only, please check.)

Transport hazard class(es)

ADR/RID: 9 (For reference only, please check.) IMDG: 9 (For reference only, please check.) IATA: 9 (For reference only, please check.)

Packing group, if applicable

ADR/RID: III (For reference only, please check.) IMDG: III (For reference only, please check.) IATA: III (For reference only, please check.)

Environmental hazards

ADR/RID: Yes

IMDG: Yes IATA: Yes

Special precautions for user

no data available

Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

Safety, health and environmental regulations specific for the product in question European Inventory of Existing Commercial Chemical Substances (EINECS)

Listed.

EC Inventory

Listed.

United States Toxic Substances Control Act (TSCA) Inventory

Listed.

China Catalog of Hazardous chemicals 2015

Not Listed.

New Zealand Inventory of Chemicals (NZIoC)

Listed.

(PICCS)

Not Listed.

Vietnam National Chemical Inventory

Not Listed.

IECSC)

Not Listed.

Korea Existing Chemicals List (KECL)

Listed.

SECTION 16: Other information

Abbreviations and acronyms

CAS: Chemical Abstracts Service

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulation concerning the International Carriage of Dangerous Goods by Rail

IMDG: International Maritime Dangerous Goods

IATA: International Air Transportation Association

TWA: Time Weighted Average

STEL: Short term exposure limit

LC50: Lethal Concentration 50%

LD50: Lethal Dose 50%

EC50: Effective Concentration 50%

References

IPCS - The International Chemical Safety Cards (ICSC), website: http://www.ilo.org/dyn/icsc/showcard.home

HSDB - Hazardous Substances Data Bank, website: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm

IARC - International Agency for Research on Cancer, website: http://www.iarc.fr/

eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=O&request_locale=en

CAWEO Chemicals, website: http://cameochemicals.noaa.gov/search/simple

ChemIDplus, website: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp

ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: http://www.phmsa.dot.gov/hazmat/library/erg

Germany GESTIS-database on hazard substance, website: http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp

ECHA - European Chemicals Agency, website: https://echa.europa.eu/

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