

1. Identification

Product identifier	Promethazine Hydrochloride	
Other means of identification		
Catalog number	1570009	
Chemical name	10H-Phenothiazine-10-ethanamine, N,N,alpha-trimethyl-, monohydrochloride	
Synonym(s)	Proazamine chloride	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 1
	Sensitization, skin	Category 1
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement	Harmful if swallowed. Causes serious eye damage. May cause an allergic skin reaction.	
Precautionary statement		
Prevention	Wash thoroughly after handling. Wear eye/face protection. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.	
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.	
Storage	Not available.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Promethazine Hydrochloride	Proazamine chloride	58-33-3	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes. May cause allergic skin reaction.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Do not induce vomiting. Perform gastric lavage. Administer activated charcoal as a slurry. For cardiac arrhythmia, administer phenytoin intravenously. For tachydysrhythmia, administer sodium bicarbonate. For torsades de pointes in hemodynamically unstable patients, treat with cardioversion. For torsades de pointes in stable patients, treat with magnesium, isoproterenol, and/or atrial overdrive pacing. Correct fluid and electrolyte disturbances. For hypotension, administer intravenous fluids, norepinephrine or phenylephrine. Do not use epinephrine. For convulsions, administer an anticonvulsant such as benzodiazepine. Monitor ECG. Do not use barbiturates. For dystonic reactions, administer benztropine or diphenhydramine. For neuroleptic malignant syndrome, treat with cooling and bromocriptine. Monitor acid-base status. Monitor fluid balance, serum electrolytes, CPK, liver enzymes, and renal functions. Dialysis will not effectively remove this material.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Foam. Dry chemical or CO ₂ .
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Promethazine Hydrochloride (CAS 58-33-3)	TWA	0.025 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other

For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White to faintly yellow crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Practically odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

431.6 - 449.6 °F (222 - 232 °C) (decomposes)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility in water

Freely soluble.

Partition coefficient (n-octanol/water)	-0.72
Auto-ignition temperature	734 °F (390 °C)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Ethylamine phenothiazine derivative.
Molecular formula	C17H20N2S . HCl
Molecular weight	320.88
pH in aqueous solution	4 - 5 (5% solution) 5.3 (10% solution)
Solubility (other)	Freely soluble in hot dehydrated alcohol, in methylene chloride, and in chloroform. Practically insoluble in ether, in acetone, and in ethyl acetate.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents. Alkaline metals. Isocyanates.
Hazardous decomposition products	NOx. SOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	May cause an allergic skin reaction.
Eye contact	Causes serious eye damage.

Symptoms related to the physical, chemical, and toxicological characteristics Muscle spasms. Stiffness. Uncontrolled movements. Difficulty breathing. Difficulty speaking or swallowing. Loss of balance. Trembling. Facial twitches. Visual disturbances. Pinpoint pupils. Yellow eyes and/or skin. Dizziness. Drowsiness. Dry mouth. Constipation. Nasal congestion. Urinary problems. Skin sensitivity to sunlight. Skin rash. Change in menstrual cycle. Swelling or tenderness of breasts. Weight gain. Vomiting. Weakness. Incoordination. Disorientation. Convulsions. It is not known if this material causes the same effects..

Delayed and immediate effects of exposure Low blood pressure. Irregular heartbeat. Coma. Sudden death.

Chronic effects Vision problems. Skin discoloration. Hypothermia. Hyperthermia. Tolerance. Involuntary movements. Neuroleptic malignant syndrome . Stupor. It is not known if this material causes the same effects.

Cross sensitivity Persons sensitive to one phenothiazine may be sensitive to this material also.

Medical conditions aggravated by exposure Active alcoholism. Blood disorders. Respiratory disorders. Cardiovascular disorders. Pheochromocytoma. Convulsive disorders. Brain damage. Neurological disorders. Dermatoses. AIDS. Glaucoma. Parkinson's disease. Breast cancer. Hypocalcemia. Reye's syndrome. It is not known if this material causes the same effects.

Acute toxicity

Product	Species	Test Results
Promethazine Hydrochloride (CAS 58-33-3)		
Acute		
<i>Oral</i>		
LD50	Mouse	255 mg/kg
	Rat	765 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Causes serious eye damage.	

Local effects

Irritancy test
Result: Irritant
Species: Rabbit
Organ: Eye
Severity: Severe
Irritancy test
Result: Irritant
Species: Rabbit
Organ: Skin
Severity: Mild

Respiratory sensitization Due to lack of data the classification is not possible.
Skin sensitization May cause an allergic skin reaction.
Germ cell mutagenicity Based on available data, the classification criteria are not met.

Mutagenicity

Ames test in Salmonella typhimurium
Result: Negative
Chromosome aberrations in Chinese hamster ovary cells
Result: Negative
Sex-linked recessive lethal mutations in germ cells of male
Drosophila
Result: Negative

Carcinogenicity Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

3.75 - 45 mg/kg Gavage studies
Result: Not carcinogenic
Species: Mouse
Test Duration: 2 years
8.3 - 33.3 mg/kg Gavage studies
Result: Not carcinogenic
Species: Rat
Test Duration: 2 years

Reproductive toxicity Adequate and well-controlled pregnancy studies in humans have not been done. There have been reports of jaundice, over- and underactive reflexes, and abnormal movement disorders in the newborns of mothers who received phenothiazines therapeutically during pregnancy. Based on available data, the classification criteria are not met.

Reproductivity

25 mg/kg Reproductivity, Intraperitoneal administration
Result: Increased fetal mortality
Species: Rat
6.25 - 12.5 mg/kg Reproductivity, Oral administration
Result: Not teratogenic
Species: Rat

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.

Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects.
Persistence and degradability No data is available on the degradability of this product.
Bioaccumulative potential Not available.
Mobility in soil Not available.
Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Not available.

Hazardous waste code Not available.

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information**DOT**

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Promethazine Hydrochloride)
Transport hazard class(es)	9
Subsidiary class(es)	Not available.
Packing group	III

IATA

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Promethazine Hydrochloride)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packaging group	III

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

DOT; IATA

**15. Regulatory information**

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes
	Delayed Hazard - Yes
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

SARA 302 Extremely hazardous substance	No
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SARA 311/312 Hazardous chemical	No
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Other federal regulations

Safe Drinking Water Act (SDWA)	Not regulated.
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Food and Drug Administration (FDA)	Not regulated.
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US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date	02-15-2006
Revision date	03-10-2014
Version #	03
Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.