

1. Identification

Product identifier	Methdilazine Hydrochloride	
Other means of identification		
Catalog number	1408000	
Chemical name	10H-Phenothiazine, 10-[(1-methyl-3-pyrrolidinyl)methyl]-, monohydrochloride	
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		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
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 3
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement	Toxic if swallowed. May cause drowsiness or dizziness.	
Precautionary statement		
Prevention	Wash thoroughly after handling. Avoid breathing dust. Use only outdoors or in a well-ventilated area.	
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.	
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	
Other hazards which do not result in classification	None known.	

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Methdilazine Hydrochloride		1229-35-2	100

4. First-aid measures

Inhalation

Move to fresh air. Call a POISON CENTER or doctor/physician if you feel unwell.

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

Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms/effects, acute and delayed

Narcotic effects.

Indication of immediate medical attention and special treatment needed

Treatment of phenothiazine overdose should be symptomatic and supportive.

1. Do NOT induce vomiting. Perform gastric lavage. Administer activated charcoal as a slurry.
2. Control cardiac arrhythmias with intravenous phenytoin. Treat ventricular tachydsrhythmias with sodium bicarbonate.
3. For Torsades de Pointes, treat hemodynamically unstable patients with electrical cardioversion. Treat stable patients with magnesium and/or atrial overdrive pacing. Correct electrolyte abnormalities.
4. Treat hypotension with positioning, intravenous fluids, and norepinephrine or phenylephrine. Do NOT use epinephrine.
5. Treat convulsions with a benzodiazepine and phenytoin. Monitor ECG. Do NOT use barbiturates that may potentiate respiratory and CNS depression.
6. For parkinsonian effects or dystonia, administer bztropine or diphenhydramine.
7. Treat neuroleptic malignant syndrome with cooling and bromocriptine.
8. Monitor acid-base status, fluid and electrolyte balance, hepatic enzymes, renal function, urine output, and cardiac function.
9. Most phenothiazines are not removed by dialysis. [Meditext; USP DI]

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. Water. Foam. Dry chemical or CO₂.

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

Use water spray to cool unopened containers. 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.

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

Biological limit values

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

Exposure guidelines	No exposure standards allocated.
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.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing 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).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Light tan crystalline powder.
Physical state	Solid.
Form	Crystalline powder.
Odor	Slight characteristic odor.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	368.6 - 372.2 °F (187 - 189 °C)
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 pressure	0.0000002 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Very soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Phenothiazine derivative.
Molecular formula	C18H20N2S . HCl
Molecular weight	332.92 g/mol
pH in aqueous solution	4.8 - 6 (1% solution)

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Toxic if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics Phenothiazines: Muscle spasms. Restlessness. Vision disturbances. Drowsiness. Dizziness. Fainting. Shock. Trouble breathing. Agitation. Confusion. Convulsions. Dilated pupils. Skin reactions. Uncontrolled movement or weakness of arms and legs. Stiffness. Difficulty in speaking of swallowing. Loss of balance. Inability to move eyes. Shuffling walk. Trembling and shaking of hands and fingers. Change in reflex. Uncontrolled movements of mouth and tongue. Constipation. Difficult urination. Vomiting. Abnormal heartbeat. Nasal congestion. Decreased sweating. Dry mouth. Changes in menstrual cycle. Decreased sexual ability. Unusual milk secretion. Swelling or pain in breasts. Weight gain.

Delayed and immediate effects of exposure Phenothiazines: Coma. Extrapyrarnidal effects. Low blood pressure. Hypothermia or hyperthermia. Central nervous system toxicity. Cardiac toxicity. Respiratory depression. Sudden death. Clumsiness. Unsteadiness. Flushing. Severe drowsiness. Severe dryness of mouth, nose, or throat.

Cross sensitivity Persons sensitive to other phenothiazines may be sensitive to this material also.

Medical conditions aggravated by exposure Phenothiazines: Active alcoholism. Blood, liver, kidney, respiratory, or cardiovascular disorders. Pheochromocytoma. History of convulsive disorders, brain damage, neuroleptic malignant syndrome, or dermatoses. Acquired immune deficiency syndrome (AIDS). Glaucoma. Parkinson's disease. Reye's syndrome. Breast cancer. Hypocalcemia. Exposure to extreme heat or phosphorus insecticides.

Acute toxicity Toxic if swallowed.

Product	Species	Test Results
---------	---------	--------------

Methdilazine Hydrochloride (CAS 1229-35-2)

Oral

LD50	Mouse	190 mg/kg
	Rat	260 mg/kg

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Due to lack of data the classification is not possible.

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

Germ cell mutagenicity Due to lack of data the classification is not possible.

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.

Reproductive toxicity Due to lack of data the classification is not possible.
Phenothiazines have been reported to cause jaundice and extrapyramidal symptoms in infants whose mothers received these medications near term.

Specific target organ toxicity - single exposure May cause drowsiness or dizziness.

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

Aspiration hazard Not classified.

12. Ecological information

Ecotoxicity There are no data on the ecotoxicity of this product.

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	Dispose of in accordance with local regulations.
Hazardous waste code	Not regulated.
Waste from residues / unused products	Dispose of in accordance with local regulations. 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	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Methdilazine Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III

IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Methdilazine Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III

Other information

Passenger and cargo aircraft Allowed.

Cargo aircraft only Allowed.

Transport in bulk according to Not available.

Annex II of MARPOL 73/78 and the IBC Code

DOT; IATA



15. Regulatory information

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

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. California Proposition 65

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)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
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)	No
Korea	Existing Chemicals List (ECL)	No
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	No

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

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date 03-10-2004

Revision date 09-09-2015

Version # 03

Further information Not available.

Disclaimer USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

Revision Information Product and Company Identification: Disclosure Overrides
Hazard(s) identification: Hazard statement
Physical & Chemical Properties: Multiple Properties
Toxicological information: Germ cell mutagenicity
Transport Information: Material Transportation Information
Regulatory information: California Prop 65
Regulatory information: US state regulations
GHS: Classification