



SAFETY DATA SHEET

1. Identification

Product identifier	Methotrimeprazine	
Other means of identification		
Catalog number	1415006	
Chemical name	10H-Phenothiazine-10-propanamine, 2-methoxy-N,N, beta-trimethyl-, (-)-	
Synonym(s)	Levomeprazine * levomepromazine	
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
	Specific target organ toxicity, single exposure	Category 1 (heart)
	Specific target organ toxicity, repeated exposure	Category 1 (nervous system)
OSHA hazard(s)	Not classified.	

Label elements



Signal word	Danger
Hazard statement	Harmful if swallowed. Causes damage to organs (heart). Causes damage to organs (nervous system) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
Response	If swallowed: Call a poison center/doctor// if you feel unwell. Rinse mouth. If exposed: Call a poison center/doctor/medical professional.
Storage	Store locked up.
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	%
Methotrimeprazine	Levomeprazine levomepromazine	60-99-1	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and plenty of water. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth thoroughly. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
Most important symptoms/effects, acute and delayed	Decrease in motor functions. Behavioral changes.

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 tachydysrhythmias 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	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
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	Cool containers exposed to flames with water until well after the fire is out.

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. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. 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. Wash spill site.

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).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Fine white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Practically odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Approximately 126 ° 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 density	Not available.
Relative density	Not available.
Solubility in water	20 mg/l Practically insoluble.
Partition coefficient (n-octanol/water)	4.68
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Other information

Chemical family	Aliphatic phenothiazine.
Molecular formula	C ₁₉ H ₂₄ N ₂ O ₂ S
Molecular weight	328.47
Solubility (other)	Freely soluble in chloroform, in ether, and in boiling alcohol; sparingly soluble in methanol.

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 mineral acids. Strong bases.
Hazardous decomposition products	NO _x , SO _x . 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	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
Dizziness when standing
For phenothiazines: Abnormal heartbeat. Sudden death. Involuntary movement (muscle spasms; uncontrolled body movements; difficulty breathing, speaking, or swallowing; loss of balance; trembling or shaking hands and fingers; shuffling walk; unusual facial expressions; eyelid spasms; twisting of neck, trunk, arms, or legs). Rigidity. Weakness. Incoordination. Dizziness. Drowsiness. Disorientation. Pinpoint pupils. Yellow eyes and/or skin. Dry mouth. Constipation. Nasal congestion. Decreased sweating. Difficulty urinating. Increased sensitivity of skin or eyes to sunlight. Skin rash. Changes in menstrual period. Swelling or pain in breasts or milk secretion. Weight gain. Vomiting. Convulsions. Coma.

Delayed and immediate effects of exposure
Orthostatic hypotension.
For phenothiazines: Extrapyrarnidal effects. Motor restlessness. Vision changes. Low blood pressure. Hypothermia or hyperthermia. Central nervous system toxicity. Cardiac toxicity. Respiratory depression.

Chronic effects
For phenothiazines: Skin and eye discoloration. Tardive dyskinesia.

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

Medical conditions aggravated by exposure
For 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

Product	Species	Test Results
Methotrimeprazine (CAS 60-99-1)		
Acute		
<i>Oral</i>		
LD50	Mouse	370 mg/kg
	Rat	1100 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 sensitization
Due to lack of data the classification is not possible.

Skin sensitization
Due to lack of data the classification is not possible.
Contact dermatitis has been reported in the literature.

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 product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Phenothiazines produce an elevation in prolactin concentrations. In vitro studies show about 1/3 of human breast cancers are prolactin-dependent. Studies in rodents found an increase in mammary tumors after long-term administration of antipsychotic medications. Early epidemiological studies did not show an association between chronic administration of antipsychotics and breast cancer in women. A later study found a modest dose-related increased risk of breast cancer in women using antipsychotic dopamine antagonists. The available evidence is inconclusive.

Reproductive toxicity Due to lack of data the classification is not possible. There have been reports of prolonged jaundice, under or overactive reflexes, movement disorders, and withdrawal effects (runny nose, vomiting, difficulty breathing) in newborns exposed to phenothiazines in utero.

Reproductivity

Multi-generational animal study
Result: Possible anti-fertility effect; successive generations had smaller litter sizes than controls.

Specific target organ toxicity - single exposure Causes damage to organs (heart).

Specific target organ toxicity - repeated exposure Causes damage to organs (nervous system) through prolonged or repeated exposure.

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

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 This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.

Local disposal regulations Not available.

Hazardous waste code Not regulated.

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

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

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

15. Regulatory information

US federal regulations One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical	No	
Other federal regulations		
Safe Drinking Water Act (SDWA)	Not regulated.	
Food and Drug Administration (FDA)	Not regulated.	
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)	No
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
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)

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

Issue date	06-02-2006
Revision date	05-10-2013
Version #	02
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	This document has undergone significant changes and should be reviewed in its entirety.