

1. Identification

Product identifier	Prochlorperazine Maleate	
Other means of identification		
Catalog number	1566001	
Chemical name	10H-Phenothiazine, 2-chloro-10-[3-(4-methyl-1-piperazinyl)propyl]-, (Z)-2-butenedioate (1:2)	
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 4
	Serious eye damage/eye irritation	Category 1
	Specific target organ toxicity, single exposure	Category 1 (heart)
	Specific target organ toxicity, repeated exposure	Category 1 (nervous system)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Harmful if swallowed. Causes serious eye damage. Causes damage to organs (heart). Causes damage to organs (nervous system) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Wash thoroughly after handling. Wear eye/face protection.
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 exposed: Call a poison center/doctor. Get medical advice/attention if you feel unwell.
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.
Other hazards which do not result in classification	None known.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Prochlorperazine Maleate		84-02-6	100

4. First-aid measures

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Get medical attention immediately.
Skin contact	Immediately flush skin with plenty of water. Get medical attention immediately.
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.
Ingestion	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Never give anything by mouth to a victim who is unconscious or is having convulsions. Rinse mouth thoroughly. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Serious eye damage. Nervous system effects. Heart rhythm abnormalities.
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 benzotropine 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. 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. 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

Exposure limit values

Industrial Use

Material

Type

Value

Prochlorperazine Maleate
(CAS 84-02-6)

TWA

0.03 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. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

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. This material is extremely irritating. 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 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

White or pale yellow crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Practically odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

442.4 °F (228 °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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Practically insoluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	10-(Piperazinylpropyl)phenothiazine
Molecular formula	C20H24ClN3S . 2C4H4O4
Molecular weight	606.09
pH in aqueous solution	3 - 4 (saturated solution)
Solubility (other)	Practically insoluble in ethanol; slightly soluble in warm chloroform and in methanol; insoluble in ether and in toluene.

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	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	Classification not possible.
Skin contact	Classification not possible.
Eye contact	Causes serious eye damage.

Symptoms related to the physical, chemical, and toxicological characteristics	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. Skin discoloration. Changes in menstrual period. Swelling or pain in breasts or milk secretion. Weight gain. Vomiting. Convulsions. Coma.
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Delayed and immediate effects of exposure	Phenothiazines: Coma. Extrapyramidal effects. Low blood pressure. Hypothermia or hyperthermia. Central nervous system toxicity. Cardiac toxicity. Respiratory depression. Sudden death.
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Chronic effects	For phenothiazines: Skin and eye discoloration. Tardive dyskinesia.
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Cross sensitivity	Persons sensitive to one phenothiazine may be sensitive to this material also.
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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.
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Acute toxicity	Harmful if swallowed.
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Product	Species	Test Results
Prochlorperazine Maleate (CAS 84-02-6)		
Acute Oral LD50	Mouse	400 mg/kg
	Rat	750 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	
Eye irritancy test	
Result: Irreversible corneal and conjunctival damage	
Species: Rabbit	
Severity: Corrosive	
Skin irritancy test	
Result: Mild irritation (abraded skin); non-irritant (intact skin)	
Species: Rabbit	
Respiratory or skin sensitization	
Respiratory sensitization	Classification not possible.
Skin sensitization	Based on available data, the classification criteria are not met.
Skin sensitization	
Guinea pig maximization test	
Result: Non-sensitizing	
Germ cell mutagenicity	Classification 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	Based on available data, the classification criteria are not met. 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. Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects. In animal studies, this material caused birth defects in the offspring when administered in high doses to the mothers during gestation.
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	No ecotoxicity data noted for the ingredient(s).
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 of contents/container in accordance with local/regional/national/international 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 dangerous goods.	

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

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 - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

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)	Yes
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)	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)

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 10-24-2005
Revision date 09-09-2015
Version # 05
Further information Not available.

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Revision Information

GHS: Classification