



Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

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PROCHLORPERAZINE MALEATE

Catalog Number: 1566001

Revision Date:

October 24, 2005

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Prochlorperazine Maleate

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW - Corrosive.

Adverse Effects: Adverse effects may include muscle spasms, restlessness, vision disturbances, drowsiness, dizziness, fainting, skin reactions, uncontrolled movement or weakness of arms and legs, stiffness, difficulty in speaking or swallowing, loss of balance control, mask-like face, inability to move eyes, shuffling walk, trembling and shaking of hands and fingers, uncontrolled movements of mouth and tongue, constipation, difficult urination, nasal congestion, decreased sweating, dry mouth, changes in menstrual period, decreased sexual ability, unusual milk secretion, swelling or pain in breasts, and weight gain. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Overdose effects may include agitation, restlessness, convulsions, irregular heartbeat, fever, low blood pressure, dry mouth, intestinal obstruction, seizures, shock, congestive heart failure, cardiac arrest, blurred vision, dilated pupils, trouble breathing, vomiting, severe central nervous system depression, and coma.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization and movement disorders.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, heart disease, active alcoholism, blood disorders, impaired liver function, Reye's syndrome, and CNS depression.

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

Target Organs: Central nervous system.

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

PROCHLORPERAZINE MALEATE

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Common Name: Prochlorperazine Maleate

Formula: C₂₀H₂₄ClN₃S · 2C₄H₄O₄

Synonym: n/f

Chemical Name: 10H-Phenothiazine, 2-chloro-10-[3-(4-methyl-1-piperazinyl)propyl]-, (Z)-2-butenedioate (1:2)

CAS: 84-02-6

RTECS Number: SO3150000

Chemical Family: 10-(Piperazinylpropyl)phenothiazine

Therapeutic Category: Anti-emetic; antipsychotic

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: Causes irritation and burns. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

Skin: May cause irritation and contact dermatitis. Avoid contact. Flush with copious quantities of water.

Ingestion: May cause irritation and toxicity. Flush out mouth with water.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Treatment of overdose should be symptomatic and supportive and may include the following::

1. Perform early gastric lavage and/or administer activated charcoal slurry with a saline cathartic. DO NOT induce vomiting.
2. Monitor body temperature and cardiovascular function for at least five days.
3. Control cardiac arrhythmias with intravenous phenytoin, give 9 to 11 mg/Kg of body weight.
4. Digitalize for cardiac failure.
5. Administer norepinephrine or phenylephrine for hypotension. DO NOT use epinephrine.
6. Control convulsions with diazepam followed by phenytoin, give 15 mg/Kg of body weight while monitoring ECG.
7. Administer benztropine or diphenhydramine to manage acute parkinson-like symptoms that may occur. [USP DI 2005]

SECTION 5 - FIREFIGHTING MEASURES

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

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: 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

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. Wash thoroughly after handling.

Storage: Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White or pale yellow crystalline powder; practically odorless.

Odor Threshold: n/f

pH: 3 - 4 (saturated solution)

Melting Range: 228° C

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Practically insoluble

Fat Solubility: n/f

Other Solubility: Practically insoluble in alcohol; slightly soluble in warm chloroform.

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C₂₀H₂₄CIN₃S · 2C₄H₄O₄

Molecular Weight: 606.1

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to air, light, and moisture.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition, material emits very toxic fumes of Cl-, Nox, and SOx. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 750 mg/kg

Oral Mouse: LD50: n/f

Other Toxicity Data: n/f

Irritancy Data: Rabbit/skin: mild (abraded skin)

Corrosivity: Rabbit/eye: corrosive

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: Tumorigenicity: Prochlorperazine salts are antipsychotics, and these medications elevate prolactin concentrations; the elevation persists during chronic administration. Tissue culture experiments indicate that approximately 1/3 of human breast cancers are prolactin-dependent in vitro, and an increase in mammary neoplasms has been found in rodents after chronic administration of antipsychotic medications. Neither clinical studies nor epidemiologic studies conducted to date, however, have shown an association between chronic administration of these medications and mammary tumorigenesis; the available evidence is considered too limited to be conclusive at this time. [USP DI 2005]

Mutagenicity Data: n/f

Reproductive and Developmental Effects: At high doses, prochlorperazine increased the incidence of cleft palate in mice and rats, but not in rabbits. There have been reports of prolonged jaundice and extrapyramidal effects in the newborns of mothers who received phenothiazines near term. Phenothiazines have shown a decrease in fertility.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State, and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

PROCHLORPERAZINE MALEATE**Catalog Number:** 1566001**Revision Date:**October 24, 2005

International Regulatory Information: EINECS #: 201-511-3
Hazard code: Xn
Risk phrases: R22, R41
Safety phrases: S25, S26, S39

SECTION 16 - OTHER INFORMATION

Revision: 24-Oct-05**Previous Revision Date:** 20-Jun-02