

# Promethazine Hydrochloride

sc-212586

Material Safety Data Sheet



The Power to Question

Hazard Alert Code Key: **EXTREME** **HIGH** **MODERATE** **LOW**

## Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

### PRODUCT NAME

Promethazine Hydrochloride

### STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

### NFPA



### SUPPLIER

Santa Cruz Biotechnology, Inc.  
2145 Delaware Avenue  
Santa Cruz, California 95060  
800.457.3801 or 831.457.3800

### EMERGENCY:

ChemWatch  
Within the US & Canada: 877-715-9305  
Outside the US & Canada: +800 2436 2255  
(1-800-CHEMCALL) or call +613 9573 3112

### SYNONYMS

C17-H20-N2-S.HCl, "10-(3-dimethylaminoisopropyl)phenothiazine hydrochloride", "10-(2-dimethylamino)propyl)phenothiazine monohydrochloride", "N-(2-dimethylaminopropyl-1)phenothiazine hydrochloride", "10-92-dimethylaminopropyl)phenothiazine hydrochloride", "N-(2' -dimethylamino-2' -methyl)ethylphenothiazine hydrochloride", "promethazine N-(2' -dimethylamino-2' -methylethyl)phenothiazine hydrochloride", "10H-phenothiazine-10-ethanamine, N, N-alpha-trimethyl-, monohydrochloride", Atosil, Diphergan, Dorme, Fargan, Fellozin, Fenazil, Fenegan, Ganphen, HL-8700, Lergigan, Phencen, "Phenergan Hydrochloride", Piletia, Primine, Promantine, Promethiazin, Prorex, Protazine, Remsed, "3277 R.P.", "antihistamine (phenothiazine type)"

## Section 2 - HAZARDS IDENTIFICATION

### CHEMWATCH HAZARD RATINGS

		Min	Max	
Flammability:	1			
Toxicity:	2			
Body Contact:	2			
Reactivity:	1			
Chronic:	3			
			Min/Nil=0 Low=1 Moderate=2 High=3 Extreme=4	

## CANADIAN WHMIS SYMBOLS



### EMERGENCY OVERVIEW

#### RISK

Harmful by inhalation and if swallowed.  
Irritating to eyes, respiratory system and skin.

### POTENTIAL HEALTH EFFECTS

#### ACUTE HEALTH EFFECTS

##### SWALLOWED

■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.

■ Antihistamines have side effects such as sedation, stomach upset (nausea, vomiting, diarrhea or constipation), blurred vision, ringing in the ears, mood changes, irritability, nightmares, loss of appetite, difficulty urinating, dry mouth, chest tightness and tingling, heaviness and weakness in the hands, nervousness, restlessness, irritability, feeling of well-being, disturbed eye movements, difficulties moving the face, "pins and needles", palpitations, faintness, increased heart rate, uncommonly irregular heart rhythms, lung swelling, and disturbed sleep and dreaming. Treatment may cause side effects within 15 minutes including a dry mouth and throat, blocked nose, wheeze, thick phlegm, fever, sweating, smell disturbances, skin flushing, double vision and dilated pupils.

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■ Hypotension is more likely with phenothiazine sedatives with an aliphatic (dimethylaminopropyl) side-chain.

■ Phenothiazine sedatives and related tranquilizers cause central depression though less so than barbiturates and benzodiazepines. Side effects include dry mouth, constipation, urinary retention, dilated pupils, agitation, sleep disturbance, depression, convulsion, blocked nose, fast heart rate, ECG changes, low blood pressure, pinpoint pupils, blurred vision, and sexual dysfunction.

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##### EYE

■ This material can cause eye irritation and damage in some persons.

##### SKIN

■ This material can cause inflammation of the skin on contact in some persons.

■ The material may accentuate any pre-existing dermatitis condition.

■ Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.

■ Open cuts, abraded or irritated skin should not be exposed to this material.

■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

■ This material is a photosensitizer. Certain individuals working with this substance may show allergic reaction of the skin under sunlight.

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##### INHALED

■ Inhalation of dusts, generated by the material, during the course of normal handling, may be harmful.

■ The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

### CHRONIC HEALTH EFFECTS

■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

There is limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population.

There is some evidence that human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

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Long-term use of antihistamines can cause sugar in the urine, obstructive jaundice, skin discoloration associated with loss of platelets, early periods, loss of milk production, breast development in males and decreased sex drive. Disturbances in the blood include anemia, loss of white blood cells and platelets.

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Wide area external application of antihistamines can cause various side effects, including sensitization and eczema.

Oral administration of phenothiazines with an aliphatic side chain, during the first three months of pregnancy, has been associated with malformations amongst offspring.

Prolonged use of phenothiazines may discolor the eye or skin; cloudiness in the cornea or lens can occur. There can be allergic reactions.

### Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
promethazine hydrochloride	58-33-3	>98

### Section 4 - FIRST AID MEASURES

#### SWALLOWED

· IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. · Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

#### EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

#### SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

#### INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

#### NOTES TO PHYSICIAN

■ In severe overdose of antihistamines, the stomach should be emptied by aspiration and lavage. Emetics should not be used.

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Following recent ingestion of an overdose of phenothiazine sedatives, the stomach should be emptied by gastric lavage, and aspiration. Management should include intensive symptomatic, and supportive therapy.

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### Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

#### EXTINGUISHING MEDIA

· Water spray or fog.  
· Foam.

#### FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.  
· Wear full body protective clothing with breathing apparatus.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 800 metres in all directions.

#### GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.  
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.  
Combustion products include: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), hydrogen chloride, phosgene, nitrogen oxides (NO<sub>x</sub>), sulfur oxides (SO<sub>x</sub>), other pyrolysis products typical of burning organic material.  
May emit poisonous fumes.

#### FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

#### PERSONAL PROTECTION

Glasses:

Gloves:

1.BUTYL 2.NATURAL RUBBER 3.PVC

Respirator:

Particulate

## Section 6 - ACCIDENTAL RELEASE MEASURES

### MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

### MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Emergency Responders and tell them location and nature of hazard.

## Section 7 - HANDLING AND STORAGE

### PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
  - Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
  - In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

### RECOMMENDED STORAGE METHODS

#### ■ Glass container.

- Lined metal can, Lined metal pail/drum
- Plastic pail.

For low viscosity materials

- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

### STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.

Protect from light.

## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE CONTROLS

The following materials had no OELs on our records

- promethazine hydrochloride: CAS:58-33-3

### PERSONAL PROTECTION



### RESPIRATOR

Particulate

Consult your EHS staff for recommendations

### EYE

- For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation

immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

## HANDS/FEET

■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.

· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.

· Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

· Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.

· Double gloving should be considered.

· PVC gloves.

· Protective shoe covers.

· Head covering.

## OTHER

· For quantities up to 500 grams a laboratory coat may be suitable.

· For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.

· For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

· For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

· Eye wash unit.

· Ensure there is ready access to an emergency shower.

· For Emergencies: Vinyl suit.

## ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

# Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

## PHYSICAL PROPERTIES

Solid.

Mixes with water.

State	Divided solid	Molecular Weight	320.9
Melting Range (°F)	440.6- 446 (decomp)	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

## APPEARANCE

White or faintly yellow, odourless, crystalline powder with intensely bitter taste; mixes with water (1:0.6), alcohol (1:9), chloroform (1:2).

# Section 10 - CHEMICAL STABILITY

## CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.

## STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

## Section 11 - TOXICOLOGICAL INFORMATION

PROMETHAZINE HYDROCHLORIDE

### TOXICITY AND IRRITATION

PROMETHAZINE HYDROCHLORIDE:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

#### TOXICITY

#### IRRITATION

Intraperitoneal (rat) LD50: 170 mg/kg Nil Reported

Subcutaneous (rat) LD50: 400 mg/kg

Intravenous (rat) LD50: 15 mg/kg

Oral (mouse) LD50: 255 mg/kg

Intraperitoneal (mouse) LD50: 160 mg/kg

Subcutaneous (mouse) LD50: 240 mg/kg

Intravenous (mouse) LD50: 50 mg/kg

Subcutaneous (dog) LD50: 250 mg/kg

Intraperitoneal (g. pig) LD50: 35 mg/kg

Intravenous (g.pig) LD50: 42.5 mg/kg

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

Sleep, convulsions, excitement, changes in motor activity, stiffness, rigidity, respiratory tract changes, effects on fertility, foetotoxicity recorded.

## Section 12 - ECOLOGICAL INFORMATION

This material and its container must be disposed of as hazardous waste.

### Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
promethazine hydrochloride	HIGH		LOW	LOW

## Section 13 - DISPOSAL CONSIDERATIONS

### Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

‡ Puncture containers to prevent re-use and bury at an authorized landfill.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and

recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

· Recycle wherever possible.

· Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

## Section 14 - TRANSPORTATION INFORMATION

DOT:

Symbols: None Hazard class or Division: 6.1

Identification Numbers: UN3249 PG: III

Label Codes: 6.1 Special provisions: T1, TP33

Packaging: Exceptions: 153 Packaging: Non- bulk: 213

Packaging: Exceptions: 153 Quantity limitations: 5 kg

Passenger aircraft/rail:

Quantity Limitations: Cargo 5 kg Vessel stowage: Location: C  
aircraft only:

Vessel stowage: Other: 40

Hazardous materials descriptions and proper shipping names:

Medicine, solid, toxic, n.o.s.

### Air Transport IATA:

ICAO/IATA Class: 6.1 ICAO/IATA Subrisk: None

UN/ID Number: 3249 Packing Group: III

Special provisions: A3

Cargo Only

Packing Instructions: 615 Maximum Qty/Pack: 5 kg

Passenger and Cargo Passenger and Cargo

Packing Instructions: 613 Maximum Qty/Pack: 5 kg

Passenger and Cargo Limited Quantity Passenger and Cargo Limited Quantity

Packing Instructions: Y613 Maximum Qty/Pack: 5 kg

Shipping Name: MEDICINE, SOLID, TOXIC, N.O.S.(CONTAINS  
PROMETHAZINE HYDROCHLORIDE)

### Maritime Transport IMDG:

IMDG Class: 6.1 IMDG Subrisk: None

UN Number: 3249 Packing Group: III

EMS Number: F-A , S-A Special provisions: 221 223

Limited Quantities: 5 kg

Shipping Name: MEDICINE, SOLID, TOXIC, N.O.S.

## Section 15 - REGULATORY INFORMATION

**promethazine hydrochloride (CAS: 58-33-3) is found on the following regulatory lists;**

"Canada Non-Domestic Substances List (NDSL)","US Toxic Substances Control Act (TSCA) - Inventory"

## Section 16 - OTHER INFORMATION

**ND**

Substance CAS Suggested codes promethazine hydrochloride 58- 33- 3

*Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.*

■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

[www.chemwatch.net/references](http://www.chemwatch.net/references).

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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