



Safety Data Sheet

Promethazine Hydrochloride Injection, USP

Section 1: Chemical Product and Company Identification

Product Name: Promethazine Hydrochloride Injection, USP

Chemical Name(s): 10H-Phenothiazine-10-ethanamine, N,N,alpha-trimethyl-, monohydrochloride

Synonym: Proazamine chloride or Phenergan Injection

CAS Number: 58-33-3

RTECS #: SO8225000

Trade Name: *Not available*

Chemical Formula: $C_{17}H_{20}N_2S \cdot HCl$



Health	2
Fire	1
Reactivity	0
Personal Protection	E

Contact Information:

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

Technical Assistance: 607-562-2700

Online Assistance: www.x-gen.us

Emergency phone number:

National Poison Control

1-800-222-1222

**For information regarding recommended uses and restrictions on usage refer to the product package insert.

Section 2: Hazard Identification

Hazard pictograms (GHS-US):



Potential Acute Health Effects: Harmful in case of ingestion. Slightly harmful in case of skin contact (irritant) and eye contact (irritant).

Potential Chronic Health Effects: Harmful if swallowed. Do not ingest. Avoid skin contact. It may cause an allergic skin reactions. Avoid eye contact due to serious eye damage. Central nervous system depression. Avoid prolonged sun exposure after direct contact.

Carcinogenic Effects: Not available

Mutagenic Effects: Not fully evaluated. Non-mutagenic in the Ames test.

Teratogenic Effects: Not available

Developmental Toxicity: Not available

Adverse effects: Not available

Section 3: Composition and Information on Ingredients

Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Promethazine Hydrochloride	58-33-3	2.5 or 5.0
Edetate Disodium	139-33-3	0.01
Calcium Chloride	10035-04-8	0.004
Sodium Metabisulfite	7681-57-4	0.025
Phenol	108-95-2	0.5
Sodium Acetate	64-18-7	pH adjustment
Acetic Acid	64-19-7	pH adjustment
Water for injection	7732-18-5	QS

Section 4: First Aid Measures

General: 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 exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

Inhalation: If mist and/or vapor is inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Skin contact: In case of contact, immediately wash skin with plenty of water. Remove contaminated clothing and shoes. Wash clothes and thoroughly clean shoes before reuse. Seek medical attention immediately.

Eye contact: Check for and remove any contacts lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention immediately.

Ingestion: DO NOT induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious person. Loosen tight clothing such as tie, collar and/or belt. Seek medical attention immediately.

Notes to physician: Seek product package insert for complete information.

Overdose Treatment: Treatment of overdose should be symptomatic and supportive. For hypotension, administer intravenous fluids, norepinephrine or phenylephrine. Do not use epinephrine. For convulsions, administer an anticonvulsant such as benzodiazepine. Monitor ECG. Do not use

barbiturates. For dystonic reaction, administer benztropine or diphenhydramine. For neuroleptic malignant syndrome, treat with cooling and bromocriptine. Monitor acid-base status. Monitor fluid balance, serum electrolytes, CPK, liver enzymes and renal function. Dialysis will not effectively remove this material.

Section 5: Fire Fighting Measures

Flammability of the product: May combust at high temperatures.

Combustion Products: These products are carbon oxides (CO, CO²), sulfur oxides (SO², SO³).

Unusual Fire and Explosion Hazards: Product is not expected to present a fire hazard.

Extinguishing Media and instruction:

Small fire: Use DRY chemical powder. **Large fire:** Use water spray, fog or foam. May use type ABC multi-purpose extinguisher. DO NOT use water jet.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Special remarks on fire hazard: Not available

Special remarks on explosion hazard: Not available

Section 6: Accidental Release Measures

Release to land:

Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

Large Spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

Release to air: If mist or vapor is generated, wear a disposable respirator (N95), and reduce exposures by ventilating area.

Release to Water: Refer to local water authority; drain disposal is not recommended.

Protective equipment: Keep unnecessary personnel away. Wear latex or nitrile gloves, safety glasses, and a disposable mask (N95), wear protective coveralls and shoe covers for spills.

Section 7: Handling and Storage

Handling: As a general rule, when handling Promethazine Hydrochloride Injection, USP, avoid all contact and inhalation of mists, and/or vapors associated with the material.

Keep locked up. Keep away from heat, sources of ignition and oxidizing agents. Empty containers pose a fire risk, evaporate the residue under a fume hood. DO NOT ingest. Wear suitable protective clothing. Use only in accordance with directions.

Storage: Keep container tightly closed. Keep container in a cool, dry, well ventilated area (see USP CRT storage conditions). Protect from light and store at controlled room temperature 20° - 25°C (68° - 77°F). Refer to label instructions to ensure product integrity.

Incompatibilities: Keep away from strong oxidizing agents.

Section 8: Exposure Controls / Personal Protection

Engineering Controls: Use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generates fumes or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Gloves. Respirator. Be sure to use an approved/ certified respirator or equivalent. **In case of Large Spill:** Splash goggles. Full suit. Respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Respiratory Protection: Under normal use, respirators are not required. If mists or vapors are generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

Exposure limit: Not available

Section 9: Physical and Chemical Properties

Physical appearance: Liquid

Color: Clear

Molecular Weight: 320.88

Taste: Not available

Odor: Odorless

Odor Threshold: Not available

pH: 4.0 – 5.5

Melting Point: 227°C - 230°C (441°F - 446°F)

Freezing Point: Not available

Boiling Point: Not available

Flash Point: Not available

Evaporation rate: Not available

Flammability: Not available

Upper Flammable Limit: Not available

Lower Flammable Limit: Not available

Vapor Pressure: Not available

Vapor Density: Not available

Relative density: Not available

Partition Coefficient: Not available
Auto-Ignition Temperature: Not available
Decomposition Temperature: Not available

Viscosity: Not available
Dispersion Properties: Not available
Solubility: Readily soluble in water

Section 10: Stability and Reactivity

Reactivity: Stable.

Chemical stability: Stable.

Possibility of hazardous reaction: Not available

Conditions to avoid: Air, light and strong oxidizing agents

Incompatible materials: Reactive with oxidizing agents.

Hazardous decomposition products: Carbon oxides, nitrogen oxides, sulfur oxides and hydrogen chloride gas

Corrosivity: Non-corrosive in the presence of glass.

Polymerization: Not available

Section 11: Toxicological Information

Routes of exposure: Absorbed through skin, eye contact and ingestion.

Symptoms:

Short term: Toxic by ingestion. Skin sensitizer and irritant. **Long term:** Conditions aggravated by over exposure may include skin, respiratory, glaucoma, impaired liver function, central nervous system, cardiovascular, seizure, bone-marrow and gastrointestinal disorders.

Reproductive toxicity: Not available

FDA Pregnancy Category: C

Toxicity to animals:

Oral Rat: LD50: 765 mg/kg

Oral Mouse: LD50: 255 mg/kg

Measures of toxicity: Not available

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).

Section 12: Ecological Information

Ecotoxicity: Not available

Bioaccumulation potential: Not available

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The product itself and its products of degradation are not toxic.

Section 13: Disposal Information

Waste classification: Toxic liquid

Waste from residues/unused products: Dispose of waste in accordance with all applicable federal, state and local laws.

Waste Disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Section 14: Transport Information

DOT Classification: Toxic liquid

UN Number: Not available

UN Shipping name: Not available

Transport hazard class: Not available

Packing Group: III

Environmental hazard: Not available

Transport in bulk: Not available

Special precautions needed with transport: Not available

Section 15: Regulatory Information

Federal and State Regulations:

California Prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects, or other reproductive harm, which would require a warning under the statute: Promethazine Hydrochloride Injection, USP.

Promethazine TSCA 8(b) inventory: Promethazine

Other Regulations: EU EINECS List: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): Not available

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Protective Equipment: Gloves, lab coat, safety glasses and respirator. Be sure to use an approved/certified respirator or equivalent.

Section 16: Other Information

References: Not available

Created: 1/30/2015

Last Updated: 3/25/2015

Prepared & Approved by: X-GEN Pharmaceuticals, Inc., Safety Committee

The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.