

SAFETY DATA SHEET

Product Name: Promethazine Hydrochloride Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Promethazine Hydrochloride Injection
Synonyms	(10 <i>H</i> -Phenothiazine-10-ethanamine, <i>N,N,α</i> -trimethyl-, monohydrochloride, (±)-)

2. HAZARD(S) IDENTIFICATION

Emergency Overview	Promethazine Hydrochloride Injection is a solution containing promethazine hydrochloride, a sedating anti-histamine with anti-muscarinic properties. Clinically, it is used for symptomatic relief of hypersensitivity reactions (allergic rhinitis, cold and allergy symptoms, conjunctivitis, pruritic skin disorders or anaphylactic reactions), as an anti-emetic for motion sickness, and for anti-cholinergic and local anesthetic effects. In the workplace, this product should be considered irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the nervous system, cardiovascular system and blood.
---------------------------	--

U.S. OSHA GHS Classification

Physical Hazards	Hazard Class	Hazard Category
	Not Classified	Not Classified
Health Hazards	Hazard Class	Hazard Category
	STOT – RE	2

Label Element(s)

Pictogram



Signal Word

Warning

Hazard Statement(s)

May cause damage to organs through prolonged or repeated exposure

Precautionary Statement(s)

Prevention

Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Promethazine Hydrochloride
Chemical Formula C₁₇H₂₀N₂S • HCl

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Promethazine Hydrochloride	2.5	58-33-3	SO6825000

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include 0.1 mg edetate disodium, 0.04 mg calcium chloride, and not more than 5 mg monothioglycerol and 5 mg phenol. Sodium acetate-acetic acid buffer added to adjust the pH.

4. FIRST AID MEASURES

Eye Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability None anticipated for this aqueous product.

Fire & Explosion Hazard None anticipated for this aqueous product.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required for hazard control under conditions of normal product use.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Promethazine Hydrochloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 AIHA WEEL: Workplace Environmental Exposure Level
 EEL: Employee Exposure Limit.
 TWA: 8-hour Time Weighted Average.

Respiratory Protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye Protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	A clear, colorless solution
Odor	NA
Odor Threshold	NA
pH	4.9 (4.0 to 5.5)
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	NA
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), sulfur oxides (SOx), and hydrogen chloride.
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Promethazine	100	LD50	Oral	326 580 640	mg/kg mg/kg mg/kg	Mouse Rabbit Guinea Pig
Promethazine	100	LD50	Intravenous	45 40 19 27	mg/kg mg/kg mg/kg mg/kg	Rat Mouse Rabbit Guinea Pig
Promethazine Hydrochloride	100	LD50	Oral	255	mg/kg	Mouse
Promethazine Hydrochloride	100	LD50	Intravenous	15 50 42.5	mg/kg mg/kg mg/kg	Rat Mouse Guinea Pig

LD 50: Dosage that produces 50% mortality.

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. This material should be considered potentially irritating to the eyes and respiratory tract. In clinical use, adverse effects may include drowsiness and sedation, or stimulation. Other effects may include dryness of mouth, blurring of vision, dizziness or lassitude, gastrointestinal effects such as epigastric distress, nausea, diarrhea or constipation, elevated body temperature, muscle rigidity, and autonomic instability. Cardiovascular side effects are occasionally seen after injection and can include tachycardia, bradycardia, mild transient hypertension and hypotension. Effects on the skin may include dermatitis, photosensitivity, and urticaria. Hematological effects may include leukopenia, thrombocytopenia, thrombocytopenic purpura, or agranulocytosis.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product. Promethazine was not irritating in skin irritation test in rabbits.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation. Promethazine is reported to be a severe eye irritant in rabbits.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product.
Reproductive Effects	None anticipated from normal handling of this product. Studies in animals to evaluate the affect on fertility have not been conducted. Teratogenic effects have not been demonstrated in rat-feeding studies at dosages of 6.25 and 12.5 mg/kg. Daily dosages of 25 mg/kg intraperitoneally have been found to produce fetal mortality in rats.

11. TOXICOLOGICAL INFORMATION: continued

Mutagenicity	Promethazine HCl Injection was nonmutagenic in the <i>Salmonella</i> test system of Ames, and negative in an <i>in vitro</i> chromosomal aberration assay in CHO cells.		
Carcinogenicity	In 2-year (gavage) carcinogenicity studies, there was no evidence of carcinogenic activity of promethazine hydrochloride in male or female F344/N rats receiving 8.3, 16.6, or 33.3 mg/kg. There was no evidence of carcinogenic activity of promethazine hydrochloride in male B6C3F mice receiving 11.25, 22.5, or 45 mg/kg. There was no evidence of carcinogenic activity of promethazine hydrochloride in female B6C3F mice receiving 3.75, 7.5, or 15 mg/kg.		
Carcinogen Lists	IARC: Not listed	NTP: Not listed	OSHA: Not listed
Specific Target Organ Toxicity – Single Exposure	NA		
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs include the nervous system, cardiovascular system and blood.		

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product.
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

Notes:

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA
Prevention	Do not breathe vapor or spray Wash hands thoroughly after handling			
Response	Get medical attention if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.			

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD ₅₀	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: October 19, 2012
Date Revised: June 02, 2014

Disclaimer:

The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.