



MATERIAL SAFETY DATA SHEET

Product Name: Promethazine Hydrochloride Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

Emergency Telephone Hospira, Inc. CHEMTREC: 800 424-9300
224 212-2055

Product Name Promethazine Hydrochloride Injection, USP

Synonyms None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Promethazine Hydrochloride
Chemical Formula $C_{17}H_{20}N_2S \cdot HCl$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Promethazine Hydrochloride	2.5	58-33-3	SO8225000
Water	97	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview Promethazine Hydrochloride is a histamine antagonist used to treat allergies, provide sedation and prevent vomiting. Target organs are the central nervous system, eyes, skin and possibly the fetus.

Occupational Exposure Potential Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact with solution.

Signs and Symptoms Direct contact would cause eye irritation. Clinical data suggests drowsiness is the most prominent central nervous system effect.

Medical Conditions Aggravated by Exposure The available data suggest pre-existing eye ailments and hypersensitivity to promethazine. Possibly pregnancy.

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5. 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:	Non-flammable.
Fire & Explosion Hazard:	None
Extinguishing Media:	Use extinguishing media appropriate for the underlying cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.
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7. HANDLING AND STORAGE

Handling	No special handling required.
Storage	No special storage required for hazard control. For product protection store at controlled room temperature of 15-30°C (59-86°F).
Special Precautions	Protect from freezing and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Promethazine Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established STEL: Not Established	8 hr TWA: 50 mcg/m ³

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

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Respiratory Protection	Respiratory protection is not needed during normal product use.
Skin Protection	If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.
Eye Protection	Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.
Engineering Controls	Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear solution
Odor	None
Boiling Point	Not Determined
Freezing Point	Not Determined
Vapor Pressure	Not Determined
Vapor Density (Air=1)	Not Applicable
Evaporation Rate	Not Applicable
Bulk Density	Not Applicable
Specific Gravity	Not Determined
Solubility	Soluble in water, methanol, ethanol
pH	4.0 – 5.5

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	Oxidizing agents
Hazardous Decomposition Products	Oxides of nitrogen
Hazardous Polymerization	None

11. TOXICOLOGICAL INFORMATION:**Toxicity**

Ingredient(s)	Percent	Test Type	Value	Units	Species
Promethazine Hydrochloride	100	LD50	255	mg/kg	Mice

LD50 is the dosage producing 50% mortality.

Product contains approximately 2.5% Promethazine Hydrochloride.

Mutagenicity	Negative in the Ames test.
Target Organ Effects	Target organs are the central nervous system, eyes, skin and possibly the fetus.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity	Not determined.
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13. DISPOSAL CONSIDERATIONS:

Waste Disposal 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

DOT Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status Not Regulated

CERCLA Status Not Regulated

SARA Status Not Regulated

RCRA Status Not Regulated

PROP 65 (Calif.) Not Regulated

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

16. OTHER INFORMATION:

MSDS Coordinator Global Occupational Toxicology

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Disclaimer:

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