

## MATERIAL SAFETY DATA SHEET

Product Name: Promethazine Hydrochloride Injection, USP

# 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name Hospira, Inc.

And Address 275 North Field Drive

Lake Forest, Illinois 60045

**USA** 

**Emergency Telephone** CHEMTREC: 800 424-9300

**Hospira, Inc.** 224 212-2055

**Product Name** Promethazine Hydrochloride Injection, USP

Synonyms None

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Ingredient Name** Promethazine Hydrochloride

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Promethazine Hydrochloridee	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

The available data suggest pre-existing eye ailments and hypersensitivity

**Aggravated by Exposure** to promethazine. Possibly pregnancy.

# Product Name: Promethazine Hydrochloride Injection, USP

## 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.

#### 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** 

	<b>Exposure limits</b>			
Component	OSHA-PEL	ACGIH-TLV	Hospira EEL	
Promethazine Hydrochloride	8 hr TWA: Not	8 hr TWA: Not Established	8 hr TWA: 50 mcg/m3	
	Established	STEL: 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.

EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

# Product Name: Promethazine Hydrochloride Injection, USP

**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 Clear solution

State

**Odor** None

Boiling Point
Not Determined
Freezing Point
Not Determined
Vapor Pressure
Not Determined
Vapor Density (Air=1)
Evaporation Rate
Bulk Density
Not Applicable
Not Applicable
Not Applicable
Not Applicable
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** Oxides of nitrogen

Decomposition Products Oxides of illuogen

**Hazardous** None

**Polymerization** 

# 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.

## Product Name: Promethazine Hydrochloride Injection, USP

# 13. DISPOSAL CONSIDERATIONS:

**Waste Disposal** Disposal should be performed in accordance with the federal, state or local

regulatory requirements.

**Container Handling** Dispose of container and unused contents in accordance with federal, state,

and Disposal and local regulations.

# 14. TRANSPORTATION INFORMATION

**DOT** Not Regulated

Notes: DOT - US Department of Transportation Regulations

## 15. REGULATORY INFORMATION

TSCA Status

CERCLA Status

Not Regulated
Not Regulated
Not Regulated
RCRA Status

Not Regulated
Not Regulated
Not Regulated
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

Date Prepared September 15, 2005 Date Revised October 21, 2008

#### 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.