3157-83

WEST-WARD

Material Safety Data Sheet

Revision date: 10/13/2011
Print date: 10/13/2011

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Promethazine HCl Injection, USP
Product code: NDC 0641-6082-01, NDC 0641-6082-25,NDC 0641-6083-01, NDC 0641-6083-25, NDC 0641-6084-01, NDC 0641-6084-25,NDC 0641-6085-01, NDC 0641-6085-25, NDC 0641-1495-31, NDC 0641-1495-35,NDC 0641-1496-31, NDC 0641-1496-35, NDC 0641-0948-31, NDC 0641-0948-35,NDC 0641-0949-31, NDC 0641-0949-35, NDC 0641-0928-21, NDC 0641-0928-25,NDC 0641-0929-21, NDC 0641-0929-25, NDC 0641-0955-21, NDC 0641-0955-25,NDC 0641-0956-21, NDC 0641-0956-25, NDC 0641-6099-01, NDC 0641-6099-25

Synonyms: Phenergan® (promethazine HCl) Injection
Chemical Family: Anticholinergic Agent. Antihistaminic Agent. Antiemetic. Sedative.
Product Type: Regulated Prescription Drug
Container Information: 1 ml vials or ampuls.
Product Use: Pharmaceutical.

Supplier:
WEST-WARD PHARMACEUTICALS
EATONTOWN, NJ 07724

Emergency telephone number: CHEMTREC: USA & Canada (800) 424-9300 OUTSIDE USA +1 703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Promethazine Hydrochloride 58-33-3	2.5-5	None	None
Phenol 108-95-2	<1	UN2821	C;R34 T;R24/25
Edetate Disodium 139-33-3	<0.1	None	None
Sodium Metabisulfate 7681-57-4	<0.05	None	None
Calcium Chloride 10043-52-4	<0.01	None	None
Water 7732-18-5	>94	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: WARNING! HARMFUL IF SWALLOWED. Do not ingest. Avoid skin contact. Avoid eye contact. Central Nervous System depression. Avoid prolonged sun exposure after direct contact.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation:	Inhalation not likely under normal use conditions.
Ingestion:	Harmful if swallowed.
Skin contact:	Can cause skin irritation.
Eye contact:	Can cause eye irritation.

4. FIRST AID MEASURES

Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
Notes to physician:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available.
Flash point:	Not determined
Autoignition temperature:	Not available
Flammable limits in air-lower (%):	Not available
Flammable limits in air-upper (%):	Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).
Environmental precautions:	No information available.
Methods for cleaning up:	If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Do not ingest. Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

Storage:

Technical measures/storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F). Protect from light.

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Promethazine Hydrochloride 58-33-3	None	None	None	None	None	None
Phenol 108-95-2	= 5 ppm TWA = 19 mg/m³ TWA	None	None	= 5 ppm TWA	None	None
Edetate Disodium 139-33-3	None	None	None	None	None	None
Sodium Metabisulfate 7681-57-4	None	None	None	= 5 mg/m³ TWA	None	None
Calcium Chloride 10043-52-4	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: Provide general or local exhaust ventilation.

Personal protective equipment:

Respiratory protection: Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits).

Eye protection: Safety glasses with side-shields. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Liquid
Appearance:	Aqueous solution
Color:	Colorless
Odor:	Not available.
pH:	4.0 - 5.5
Molecular weight:	Not available.
Boiling point/range:	Not available.
Melting point/range:	Not available.
Density:	Not available.
Vapor pressure:	Not available.
Evaporation rate:	Not available.
Solubility:	Not available.
Partition coefficient (n-octanol/water):	Not available.
Viscosity:	Not available.
% Volatile by Volume:	Not available.

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	Not applicable
Hazardous decomposition products:	Not available.
Materials to avoid:	Acids. Bases. Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Promethazine Hydrochloride 58-33-3	Oral LD50 Mouse = 255 mg/kg Intravenous LD50 Rat = 15 mg/kg Intravenous LD50 Mouse = 50 mg/kg
Phenol 108-95-2	Inhalation LC50 Mouse = 177 mg/m^3 Oral LD50 Mouse = 270 mg/kg Inhalation LC50 Rat = 316 mg/m^3 Oral LD50 Rat = 317 mg/kg Dermal LD50 Rabbit = 630 mg/kg
Edetate Disodium 139-33-3	Oral LD50 Rat = 2 gm/kg Oral LD50 Mouse = 2050 mg/kg
Sodium Metabisulfate 7681-57-4	Oral LD50 Rat > 2 g/kg
Calcium Chloride 10043-52-4	Oral LD50 Rat = 1 gm/kg Oral LD50 Mouse = 1940 mg/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

Acute toxicity: Signs and symptoms of anticholinergic toxicity include: lethargy, sleepiness, dizziness, coma, confusion, agitation, hallucinations, convulsions, visual disturbances, dry flushed skin, dry mouth, decreased bowel sounds, urinary retention, increased heart rate, high blood pressure, and supraventricular arrythmias (loss of rhythm above the ventricles). Irritation potential to skin, eyes, and mucous membranes.

Chronic toxicity: Contains material which causes damage to the following organs: kidneys, lungs, liver, mucous membranes, spleen, skin, eye, lens or cornea, and pancreas. Target Organs: Bone marrow, Nervous system.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.

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

Reproductive toxicity: Fetotoxic at high doses based upon animal data. See patient package insert for additional information.

FDA Pregnancy Catagory C

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Etoxicity Data
Promethazine Hydrochloride 58-33-3	None.	None.	None.	None.
Phenol 108-95-2	= 23.0 mg/L LC50 water flea	LC50 (96 hr) fathead minnow:24 mg/L:;LC50 (96 hr) rainbow trout:8.9 mg/L:Flow-through, 13-15 °C, pH 7.7-8.1, 565-700 mg/L CaCO3.;LC50 (96 hr) bluegill:23.88 mg/L:Static, 25 °C, pH 7.5, 20.0 mg/L CaCO3.	None.	= 28.8 mg/L EC50 Photobacterium phosphoreum = 31.6 mg/L EC50 Photobacterium phosphoreum
Edetate Disodium 139-33-3	None.	LC50 (96 hr) bluegill:159 mg/L:Static.	None.	None.
Sodium Metabisulfate 7681-57-4	None.	None.	None.	None.
Calcium Chloride 10043-52-4	None.	None.	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name:	None
UN Number:	None
DOT Packing Group:	None
DOT Hazard class:	None

TDG (Canada):

TDG Proper shipping name:	None
TDG UN/NA Number:	None
TDG Packing Group:	None
TDG Hazard class:	None

ADR/RID:

ADR Official Transport Name:	None
ADR Proper shipping name:	None
ADR UN/NA number:	None
ADR Hazard Class:	None

ICAO / IATA:

IATA Proper shipping name:	None
IATA UN NUMBER	None
IATA Primary Hazard	None
IATA Packing group:	None
ICAO ERG Code:	None

IMO / IMDG:

IMDG Proper Shipping Name:	None
IMDG Hazard Class and Division:	None
IMDG Packing Group:	None
IMDG Subsidiary Risks:	None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Promethazine Hydrochloride	2.5-5	Not Listed	Not Listed	Not Listed	Not Listed
Phenol	<1	waste number U188	= 454 kg final RQ = 1000 lb final RQ = 45.4 kg final RQ = 100 lb final RQ = 0.454 kg final RQ = 1 lb final RQ	= 10,000 lb TPQ upper threshold = 500 lb TPQ lower threshold	form R reporting required for 1.0% de minimis concentration
Edetate Disodium	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Metabisulfate	<0.05	Not Listed	Not Listed	Not Listed	Not Listed
Calcium Chloride	<0.01	Not Listed	Not Listed	Not Listed	Not Listed
Water	>94	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Promethazine Hydrochloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Phenol	Not Listed	Skin	Not Listed	Toxic, Flammable	extraordinarily hazardous	environmental hazard	sn 1487
Edetate Disodium	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Metabisulfate	Not Listed	Present	Not Listed	Toxic	Present	[present]	sn 1708
Calcium Chloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product complies with DSL

EU EINECS List - This product complies with EINECS

Risk Phrases:
NONE

Safety Phrases:
NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):
Updated NDC code. Changed company name from Baxter to West-Ward Pharmaceuticals.

Additional information:
Not Available.

Prepared by: West-Ward Pharmaceuticals

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet