

# Safety Data Sheet

## Prochlorperazine Edisylate Injection (5 mg/mL)

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Common/Trade Name** : Prochlorperazine Edisylate Injection  
(5 mg/ml, 2 and 10 ml vials)

**Chemical Names** : Phenothiazine, 2-chloro-10-(3-(1-methyl-4-piperazinyl)propyl)-, ethanedisulfonate

**Synonyms** : 2-Chloro-10-(3-(1-methyl-4-piperazinyl)propyl)phenothiazine edisylate, 2-Chloro-10-(3-(4-methyl-1-piperazinyl)propyl)phenothiazine  
1,2-ethanedisulfonate, Prochlorperazine ethane disulfonate

**Manufacturer** : Emcure Pharmaceuticals Limited  
(Sterile Products Division)  
Plot No.- P-1, I.T.B.T. Park, Phase – II  
M.I.D.C Hinjwadi  
Pune-411057 (Maharashtra State)  
INDIA

**Responsible name** : N.K. Khandelwal Ph.D.

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### 2. HAZARDS IDENTIFICATION

**Routes of Entry** : Prochlorperazine Edisylate Injection may be absorbed via contact with skin or eyes, inhalation of aerosols or accidentally ingested.  
Under normal use with supervision of a physician,  
Prochlorperazine Edisylate Injection presents little hazard.

**Health Hazard (Acute & Chronic)** : Prochlorperazine Edisylate Injection is used for the treatment of severe nausea and vomiting and the management of the manifestation of psychotic disorders. Minimal adverse effect should occur from routine handling of this product. Acute signs and

symptoms of over exposure by injection or ingestion on may include drowsiness, dizziness, restlessness, severe muscle spasms, blurred vision, hypotension, cholestatic jaundice, seizures or women may experience menstrual irregularities. Product may cause allergic reactions in individuals sensitive to phenothiazines.

**Medical Conditions Generally Aggravated by Exposure:** Conditions aggravated by exposure may include nervous system disorders.

**Carcinogenicity:** NTP? NO IARC Monographs? NONE OSHA Regulated? NO

**Signs & Symptoms of Exposure:** Exposure can cause irritation to eyes, skin, and respiratory system, nausea, headache, or dizziness.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Each mL contains	CAS#	OSHA PEL	ACGIH TLT	Other Limits Recommended
Prochlorperazine Edisylate	5 mg	1257-78-9	NONE	NONE	NONE
Benzyl Alcohol	7.5 mg	100-51-6	NONE	NONE	NONE
Water for Injection	q.s.	7732-18-5	NONE	NONE	NONE

Prochlorperazine Edisylate Injection is a sterile injectable liquid drug provided in a vial.

### 4. FIRST AID MEASURES

- Eye Exposure** : Flush eyes with large volumes of water for 15 or more minutes. Get medical attention if irritation or signs of exposure are noted.
- Skin Exposure** : Remove contaminated clothing, wash skin with water and soap for 15 minutes. Get medical attention if irritation or signs of exposure are noted.
- Ingestion** : If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.
- Injection** : In cases of accidental injection, wash and disinfect area, get medical attention.

**Inhalation** : If difficulty with breathing, remove from exposure, administer oxygen.  
Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.

#### 5. FIRE FIGHTING MEASURES

**Flash Point (Method Used)** : Not Applicable

**LEL** : Not Applicable

**UEL** : Not Applicable

**Flammable Limits** : Not Applicable

**Extinguishing Media** : Use water or an ABC multi-purpose extinguisher.

**Special Fire Fighting Procedures** : As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

**Unusual Fire/Explosion Hazards:** Heat of the fire could cause vials or syringes to burst.

#### 6. ACCIDENTAL RELEASE MEASURES

**Release to Land** : Absorb Prochlorperazine Edisylate Injection with absorbent materials and dispose according to local, state, and federal guidelines.

**Release to Air** : If aerosolized, reduce exposures by ventilating area.

**Release to Water** : Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

#### 7. HANDLING AND STORAGE

**Steps to be taken in case material is released or spilled:** See Section VI above. Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

**Waste Disposal Method** : Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

**Precautions to be taken in handling and storing:** Store at controlled room temperature 15° 30°C (59°-86°F). Keep away from direct light. Follow instructions provided in packaging.

**Other Precautions** : None identified.

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Respiratory Protection** : Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Ventilation** : Handle product in a well-ventilated area.

**Protective Gloves** : Latex or nitrile

**Eye Protection** : Safety glasses

**Other Protective Clothing or Equipment:** Lab Coat

**Work/Hygienic Practices** : Wash hands following use. No eating, drinking, or smoking while handling this product.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State** : Liquid

**Specific Gravity** : Not available

**Appearance and Odor** : Clear solution

**Melting Point** : Not available

**Boiling Point** : Not available

**Evaporation Rate** : Approx. to water

**Vapor Pressure** : Not available

**Solubility in Water** : Soluble

**Vapor Density** : Not available

**pH** : 4.2 – 6.2

#### 10. STABILITY AND REACTIVITY

Stability : Stable

Incompatibility (Materials to Avoid): None identified.

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts such as oxides of carbon, nitrogen, hydrochloric and sulfuric acids at high temperatures.

Hazardous Polymerization : Will not occur

Conditions to Avoid : None identified.

## 11. TOXICOLOGICAL INFORMATION

For Prochlorperazine Edisylate Injection (active ingredient) RTECS Number XZ4810000

LD<sub>50</sub> mouse, Intraperitoneal = 177 mg/kg

LD<sub>50</sub> mouse, Subcutaneous = 320 mg/kg

LD<sub>50</sub> mouse, Oral = 400 mg/kg

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

## 12. ECOLOGICAL INFORMATION

Information is currently not available on the environmental impact of Prochlorperazine Edisylate Injection. Handle in a manner to prevent spills or releases to the environment.

## 13. DISPOSAL CONSIDERATIONS

Dispose of by incineration at an approved/permitted incinerator.

Review local, state, and federal regulations for your regulatory area.

## 14. TRANSPORT INFORMATION

Prochlorperazine Edisylate Injection is not a DOT hazardous material.

Prochlorperazine Edisylate Injection is not a DOT Marine Pollutant.

**15. REGULATORY INFORMATION**

SARA 313 listed? : NO

CERCLA listed? : NO

RCRA listed? : NO

TSCA Inventory? : NO

**16. OTHER INFORMATION**

Date prepared : June 12, 2015

1. Use of this product should be through or under the direction of a physician.

This SDS does not address therapeutic use of this material.

2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.