

SECTION 1: IDENTIFICATION

1.1. (a) Product

Identifier Product Form:

Solution

Product Name: Prochlorperazine Edisylate Injection, USP

Product Code: NDC 70069-371-25

Common/Trade Name: Prochlorperazine Edisylate Injection, USP

Chemical Name: 10H-Phenothiazine, 2-chloro-10-[3-(4-methyl-1-piperazinyl) propyl]-,1,2-ethanedisulfonate (1:1)

Container Information: Vial

Chemical Family: Antipsychotic. Antiemetic

(b) Other means of identification: None

(c) Intended Use of the Product substance/mixture: Pharmaceuticals.

1.2. Manufactured for:

Somerset Therapeutics, LLC. Somerset, NJ 08873

1.3. (e) Emergency Telephone Number, Hazardous Materials or Dangerous Goods Incident, Spill, Leak, Fire, Exposure, or Accident:

Customer Care: 1-800-417-9175

SECTION 2: HAZARDS IDENTIFICATION

2.1. (a) Classification of the Substance or Mixture: Not classified

(b) Label Elements GHS-US Labeling: None

Signal Word: No signal word.

Hazard statements: Not applicable (N/A).

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2. (c) Other Hazards: Not applicable (N/A)

(d) Unknown Acute Toxicity (GHS-US): No data available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances:

(a) Chemical Name	(b) Common Name/Synonym	(c) CAS-No	% Composition or other measurements	Impurities/Stabilizing Additives
10H-Phenothiazine, 2-chloro-10-[3-(4-methyl-1-piperazinyl) propyl]-,1,2-ethanedisulfonate (1:1)	Prochlorperazine Edisylate	1257-78-9	<1%	N/A
N/A	Benzyl Alcohol	100-51-6	<1%	Preservative
1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt, dihydrate	Sodium Saccharin	6155-57-3	<1%	Preservative
Phosphoric acid, monosodium salt, monohydrate	Sodium Phosphate	10049-21-5	<1%	Buffer
Disodium L-tartrate	Sodium Tartrate Dihydrate	868-18-8	<1%	Buffer
Water for Injection	Water for Injection	N/A	q.s. to 100%	N/A

SECTION 4: FIRST AID MEASURES

4.1. (a) Description of First Aid Measures First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

First-aid Measures After Inhalation: Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

First-aid Measures After Skin Contact: Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

First-aid Measures After Eye Contact: Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

(b) Most important symptoms and effects, both acute and delayed Symptoms/Injuries:

Irritation of eyes and mucous membranes. Gastrointestinal disturbances.

Indication of Any Immediate Medical Attention and Special Treatment Needed: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled

SECTION 5: FIRE-FIGHTING MEASURES

5.1. (a) Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal.

(b) Special Hazards Arising from the Substance or Mixture: Hazardous reactions will not occur under normal conditions.

5.2. (c) Special protective equipment and precautions for fire-fighters: Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus to protect against potential hazardous combustion and decomposition products.

Firefighting Instructions: Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. (a) Personal Precautions, Protective Equipment and Emergency Procedures General Measures Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.

For Non-emergency Personnel Protective Equipment: Avoid all unnecessary exposure. Do not breathe vapor or mist.

Protective Equipment: Use appropriate personal protection equipment (PPE). Refer to section 8.2.

Emergency Procedures: Evacuate unnecessary personnel.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. (a) Emergency Procedures: Avoid all unnecessary exposure. Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill 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.

For Emergency Responders Protective Equipment: Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

Environmental Precautions: Prevent entry to sewers and public waters.

6.2. (b) Methods and Material for Containment and Cleaning Up Methods: : Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads, or paper towels Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

6.3. (c) Reference to Other Sections: See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. (a) Precautions for Safe Handling Hygiene Measures: Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

(b) Conditions for Safe Storage, Including Any Incompatibilities Technical Measures: Comply with applicable regulations.

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

Other Guidelines: No information available

7.2. (c) Incompatible Products: Not applicable.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. (a) Exposure Limit:

Compound	Issuer	Type	Exposure Limit
Benzyl Alcohol	AIHI WEEL	TWA 8 hours	10 ppm

8.2. (b) Appropriate Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contamination at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

8.3. (c) Personal Protective Equipment: Gloves. Safety glasses.



RESPIRATORY PROTECTION: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

EYE/FACE PROTECTION: Wear safety glasses with side shields, chemical splash goggles, or full-face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

HAND PROTECTION: Wear nitrile or other impervious gloves if skin contact is possible. When the material is diluted in an organic solvent, wear gloves that provide protection against the solvent.

SKIN and BODY PROTECTION: Chemical-resistant, impervious gloves complying with an approved standard should be always worn when handling chemical products if a risk assessment indicates this is necessary. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

SPECIAL NOTE: When using, do not eat, drink, or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- 9.1. Information on Basic Physical and Chemical Properties**
- (a) Appearance (physical state. Color, etc.), : Liquid, colorless to slightly yellow
 - (b) Odor : Odorless
 - (c) Odor Threshold : Not applicable
 - (d) pH : 4.2 – 6.2
 - (e) Melting Point/freezing point : Not applicable
 - (f) Initial boiling point and boiling range : No data available
 - (g) Flash Point : No data available
 - (h) Evaporation rate : Not applicable
 - (i) Flammability (solid, gas) : No data available
 - (j) Upper/lower flammability or explosive limits : Not available
 - (k) Vapor Pressure : No data available
 - (l) Vapor Density : Not available
 - (m) Relative Density at 20 °C : Not applicable
 - (n) Solubility (ies) : Not applicable
 - (o) Partition Coefficient: N-Octanol/Water : Not applicable
 - (p) Auto-ignition temperature : No data available
 - (q) Decomposition temperature : Not applicable
 - (r) Viscosity : No data available
 - Other Information : No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. (a) **Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. (b) **Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. (c) **Possibility of Hazardous Reactions:** No hazardous reaction known under conditions of normal use.
- 10.4. (d) **Conditions to Avoid:** Heat, flames, and sparks.
- 10.5. (e) **Incompatible Materials:** Acid Bases. Oxidizing agents.
- 10.6. (f) **Hazardous Decomposition Products:** NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes underfire condition.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

(a) **Likely Route of entry:** Skin, eyes, ingestion, or inhalation. **CONTACT WITH SKIN or EYES:** May cause eye and skin irritation. **INHALATION:** May be harmful if inhaled. May cause respiratory tract irritation. **INGESTION:** Ingestion may cause adverse effects.

(b) **Symptoms related to the chemical, and toxicological characteristics:** No known significant effects or critical hazards.

(c) **Delayed and immediate effects and chronic effects from short- and long-term exposure:** No known significant effects or critical hazards.

Reproduction & Development Toxicity: No data available.

Carcinogenicity: No studies identified

(d) Acute Toxicity:

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Benzyl Alcohol	= 1230 mg/kg (Rat)	= 2000 mg/kg (Rabbit)	-

SECTION 11 CONTINUED: TOXICOLOGICAL INFORMATION

(e) Hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Hydrochloric Acid

IARC Group 3 (Not Classifiable)

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. (a) **Ecotoxicity:** Benzyl Alcohol: Acute LC 50 46000mcg/L Fresh Water; Species: Fish - Pimephales promelas -Juvenile (Fledgling, Hatchling, Weanling); Exposure:96 hours
- 12.2. (b) **Persistence and Degradability:** Not determined for product.
- 12.3. (c) **Bio accumulative Potential:** Benzyl Alcohol LogP 0.87: Potential Low.
- (d) **Mobility in Soil:** Not applicable.
- 12.4. (e) **Other Adverse Effects:** No known significant effects or critical hazards.

SECTION 13: DISPOSAL CONSIDERATIONS**13.1. Waste treatment methods:**

(a) **Sewage Disposal Recommendations:** The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

(b) **Waste Disposal Recommendations:** Dispose of waste material in accordance with all local, regional, national, and international regulations. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain someproduct residues.

SECTION 14: TRANSPORT INFORMATION

- 14.1. **In Accordance with DOT:** Not regulated for transport
- (a) **UN Number:** Not applicable
- (b) **UN Proper Shipping Name:** Not applicable.
- (c) **Transportation Hazardous Class (es):** Not applicable.
- (d) **Packing group:** Not applicable.
- (e) **Environmental Hazards (e.g., Marine pollutant):** Not regulated for transport.
- (f) **Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable.
- (g) **Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises:** Not applicable.
- 14.2. **In Accordance with IMDG:** Not regulated for transport
- 14.3. **In Accordance with IATA:** Not regulated for transport

SECTION 15: REGULATORY INFORMATION**15.1. U.S. REGULATIONS:**

TSCA 4(a) proposed test rules: 1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt TSCA 8(a) CDR Exempt/Partialexemption: Not determined

United States inventory (TSCA 8b): Not determined

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

16.1. Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

16.2. Key or legend to abbreviations and acronyms used in the safety data sheet

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)

SECTION 16 CONTINUED: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST

TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases: Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage H331 - Toxic if inhaled H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled H335 - May cause respiratory irritation H411 - Toxic to aquatic life with long lasting effects.

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