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Section 1 - Identification

- (a) **Product Identifier:** Prochlorperazine Edisylate Injection, USP (5 mg/mL; 2 and 10 mL vials)
- (b) **Product Code:** 70860-778
- Common/Trade Name:** Prochlorperazine Edisylate
- Chemical Name:** 2-Chloro-10-[3-(4-methyl-1-piperazinyl) propyl] phenothiazine 1,2-ethanedisulfonate (1:1)
- Chemical Family:** Antipsychotic – Antiemetic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **Classification:** **OSHA Classification:** While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	No Signal Word
Hazard Statements:	No known significant effects or critical hazards.

- (d) **Unknown Acute Toxicity** N/A

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Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
2-Chloro-10-[3-(4-methyl-1-piperazinyl)propyl] phenothiazine 1,2-ethanedisulfonate (1:1)	Prochlorperazine edisylate	7.54* mg per mL	1257-78-9	N/A
Monobasic sodium phosphate monohydrate	Monobasic sodium phosphate	5.0 mg per mL	7558-80-7	N/A
Sodium Tartrate Dihydrate	Sodium Tartrate Dihydrate	12 mg per mL	6106-24-7	N/A
Sodium Saccharin dihydrate	Sodium Saccharin dihydrate	1.058** mg per mL	128-44-9	N/A
Benzyl Alcohol	Benzyl Alcohol	7.5 mg per mL	100-51-6	N/A
Water For Injection	Water For Injection	q.s. to 1mL	7732-18-5	N/A
Nitrogen	Nitrogen	As required	7727-37-9	N/A

* Prochlorperazine edisylate equivalent to 5 mg of Prochlorperazine.

** Sodium Saccharin dihydrate equivalent to 0.9 mg of Sodium Saccharin.

q.s. – quantity sufficient.


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Section 4 – First Aid Measures

- Eye Exposure:** Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Skin Exposure:** Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.
- Ingestion:** Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
- Injection:** In cases of accidental injection, wash and disinfect area, seek medical attention.
- Inhalation:** Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Notes to physician** Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled. See patient package insert in shipping carton for complete information.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Use an extinguishing agent suitable for the surrounding fire.
- (b) **Hazardous Combustion Products:** This material is not expected to be combustible, based on components present.
- (c) **Special Protective Equipment / Precautions:** Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Where appropriate, collect product or firefighting water for later disposal.

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Section 6 - Accidental Release Measures

- Spill:**
- Small: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large: Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13).
- Release to Air:** Not available.
- Release to Water:** Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Refer to local and regional water authority requirements.


Section 7 - Handling and Storage

- General Handling:** Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.
- Storage Conditions:** Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Prochlorperazine Edisylate	OSHA	TLV	NE
	ACGIH	PEL	NE
	----	STEL	NE

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(b) Engineering Controls


Good general ventilation should be sufficient to control worker exposure to airborne contaminants. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

(c) Individual Protection Measures

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 Protection:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
Skin Protection:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times 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.
Other Protective Equipment:	Wear appropriate chemical resistant clothing.
Additional Exposure Precautions:	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Section 9 - Physical and Chemical Properties

(a) Appearance	Colorless liquid
(b) Odor	Not available
(c) Odor Threshold	Not available

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(d)	pH	4.2-6.2
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Not applicable
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	No specific test data related to reactivity available for this product or its ingredients.
(b)	Chemical Stability	The product is stable.
(c)	Possibility of Hazardous Reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
(d)	Conditions to Avoid	No specific data.
(e)	Incompatible Materials	Acids. bases. Oxidizing agents.
(f)	Hazardous Decomposition Products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Not available.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	No known significant effects or critical hazards.

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(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	None available.
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(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Benzyl alcohol	LD50 -	Dermal	Rabbit	2000 mg/kg
	LD50 -	Oral	Rat	1230 mg/kg

(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	Benzyl Alcohol: Acute LC50 460000 µg/L Fresh water species of Fish - <i>Pimephales promelas</i> – Juvenile (Fledgling, Hatchling, Weanling) with an exposure time of 96 hours.
(b)	Persistence and degradability	Not Available
(c)	Bioaccumulative potential	Benzyl Alcohol: LogP _{ow} 0.87 low potential.
(d)	Mobility in soil	Not available
(e)	Other Adverse Effects	Not Available


Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a)	UN Number	Not Available
(b)	UN Proper Shipping Name	Not Available
(c)	Transport Hazard Class(es)	Not Available
(d)	Packing Group	Not Available
(e)	Environmental Hazards	Not Available

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(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g)	Special Precautions	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Federal Regulations:

TSCA:

- 4(a) proposed test rules: 1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt
- 8(a) CDR Exempt/Partial exemption: Not determined
- United States inventory (TSCA 8b): Not determined.

CERCLA - Not listed

SARA 302/304: Not listed

SARA 313 – No products were found


Section 16 - Other Information

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.


For additional information contact:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these terms will apply to this SDS.
Glossary Terms will apply to this SDS. JANDRE. Once this document is printed it is an UNCONTROLLED COPY.

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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
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
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)
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 Pharmacopoeia

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WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

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All dates and times are in Eastern Standard Time.

Prochlorperazine SDS

Change Request

Name/Signature	Title	Date	Meaning/Reason
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Quality	03 Jul 2018, 12:26:19 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	01 Aug 2018, 10:44:08 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	06 Aug 2018, 12:06:43 PM	Approved