



SAFETY DATA SHEET

Section 1: Identification	
Material	Plerixafor Injection 24mg/1.2mL(20mg/mL)
Recommended use	Pharmaceutical use
Manufacturer	Hetero Labs Limited Unit VI, Sy. No.: 410 & 411, TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahabubnagar – 509301 Telangana, India
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard Statements (GHS-US/CA) <ul style="list-style-type: none">• H361- Suspected of damaging fertility or the unborn child.	
Precautionary Statements (GHS-US/CA) <ul style="list-style-type: none">• P201- Obtain special instructions before use• P202-. Do not handle until all safety precautions have been read and understood• .P280- Wear protective gloves, protective clothing, eye protection.• P308+P313- If exposed or concerned. Get medical advice/attention.• P405- Store locked up.• P501- Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.	



Other hazards	Exposure may aggravate pre-existing eye, skin, or respiratory conditions
Unknown acute toxicity (GHS US/CA)	Not applicable

Section 3: Composition/Information on Ingredients

Ingredients	CAS-No
Plerixafor	110078-46-1
Sodium Chloride	7647-14-5
Sodium hydroxide	1310-73-2
Hydrochloric acid	7647-01-0
Water for injection	7732-18-5

Section 4: First-Aid Measures

Description of first aid measures	
Inhalation	Go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists
Skin contact	Remove contaminated clothing. Drench affected area with water for at least 5 minutes. If exposed or concerned: Get medical advice /attention.
Eye contact	Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists
Ingestion	Rinse mouth. Do NOT induce vomiting. Obtain medical attention.
Most important symptoms and effects, both acute and delayed	
Inhalation	Prolonged exposure may cause irritation
Skin contact	Prolonged exposure may cause skin irritation.
Eye contact	May cause slight irritation to eyes.
Ingestion	Ingestion may cause adverse effects
Chronic symptoms	Suspected of damaging fertility or the unborn child.
Indication of any immediate medical attention and special treatment needed	
If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand	



Section 5: Fire-Fighting Measures	
Extinguishing media	
Suitable extinguishing media	Use extinguishing media suitable for surrounding type of fire
Unsuitable extinguishing media	None.
Special hazards arising from the substance or mixture	
Fire hazard	None flammable
Explosion Hazard	Product is not explosive
Reactivity	Hazardous reactions will not occur under normal conditions.
Advice for firefighters	
Precautionary Measures Fire	Exercise caution when fighting any chemical fire.
Firefighting Instructions	Use water spray or fog for cooling exposed container.
Protection During Firefighting	Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous Combustion Products	Carbon oxides, Nitrogen oxides.
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
For non-emergency personnel	
Protective Equipment	Use appropriate personal protective equipment (PPE).
Emergency Procedures	Evacuate unnecessary personnel.
For emergency personnel	
Protective Equipment	Equip clean up crew with proper protection
Emergency Procedures	Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as conditions permit. Ventilate area.
Environmental Precautions	Prevent entry to sewers and public waters.
Methods and material for containment and cleaning up	
For containment	Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
Methods for cleaning up	Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.
Reference to other sections	No additional information available



Section 7: Handling and Storage

Precautions for safe handling	Wash hands and other exposed areas with soap and water before eating, drinking or smoking and when leaving work. Obtain special instruction before use. Do not handle until all safety precautions have been read and understood. Do not get in eye, on skin, or on clothing. Do not breathe vapours, spray, mist
Conditions for safe storage, including any incompatibilities	Store vials at 25°C(77°F), excursions permitted to 15°C-30°C (59°F - 86°F)

Section 8: Exposure Controls/Personal Protection

Appropriate engineering controls	Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.
Personal Protective Equipment	Gloves, protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.
Materials for protective clothing	Chemically resistant materials and fabrics.
Hand protection	Wear protective gloves.
Eye and Face protection	Chemical safety goggles.
Skin and body protection	Wear suitable protective clothes.
Respiratory Protection	If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Other information	When using, do not eat, drink or smoke.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

Physical state	Liquid
Description	Plerixafor injection USP, 24 mg/1.2 mL (20 mg/mL) is a sterile, preservative-free, clear, colorless to pale yellow solution supplied in a 2 mL clear glass single-dose vial. NDC Number: 31722-373-31 Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Discard unused portion.



Section 10: Stability and Reactivity	
Reactivity	Hazardous reaction will not occur under normal conditions.
Chemical stability	Stable under recommended handling and storage conditions.
Possibility of hazardous reactions	Hazardous polymerization will not occur.
Conditions to avoid	Direct sunlight, extremely high or low temperatures, and incompatible materials.
Incompatible materials	Strong acids, strong bases, strong oxidizers.
Hazardous decomposition products	Thermal decomposition may produce. Carbon oxides, nitrogen oxides.
Section 11: Toxicological Information	
Information on toxicological effects	
Acute toxicity(oral)	Not classified
Acute toxicity (Dermal)	Not classified
Acute toxicity (Inhalation)	Not classified
LD50 and LC50 Data	No additional information available
Skin Corrosion/Irritation	Not classified
PH	6-7.5
Eye Damage/Irritation	Not classified
PH	6-7.5
Respiratory or Skin Sensitization	Not classified
Germ Cell Mutagenicity	Not classified
Carcinogenicity	Not classified
Specific Target Organ Toxicity (Repeated Exposure)	Not classified
Reproductive Toxicity	Suspected of damaging fertility or the unborn child.
Specific Target Organ Toxicity (Single Exposure)	Not classified
Aspiration Hazard	Not classified
Symptoms/Injuries After Inhalation	Prolonged exposure may cause irritation.
Symptoms/Injuries After Skin	Prolonged exposure may cause skin irritation.



Contact	
Symptoms/Injuries After Eye Contact	May cause slight irritation to eyes.
Symptoms/Injuries After Ingestion	Ingestion may cause adverse effects.
Chronic Symptoms	Suspected of damaging fertility or the unborn child.
Sodium chloride (7647-14-5)	
LD50 oral rat	3550 mg/kg
LD50 dermal rabbit	> 10000 mg/kg
LC50 Inhalation - Rat	> 42mg/L (Exposure time: 1 h)
Hydrochloric acid (7647-01-0)	
LD50 dermal rabbit	> 5010 mg/kg
Sodium hydroxide (1310-73-2)	
LD50 oral rat	325 mg/kg
Hydrochloric acid (7647-01-0)	
IARC group	3

Section 12: Ecological Information

Toxicity

Sodium chloride (7647-14-5)	
LC50 - Fish [1]	5560(5560-6080) mg/L (Exposure time: 96 h - Species: Lepomis macrochirus[flow-through])
EC50-Crustacea [1]	1000 mg/L (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	12946 mg/L (Exposure time: 96 h -Species: Lepomis macrochirus[static])
EC50-Crustacea [2]	340.7 (340.7-469.2) mg/L (Exposure time: 48 h



	- Species: Daphnia magna[static])
NOEC Chronic Fish	252 mg/L (species: Pimephales promelas)
Hydrochloric acid (7647-01-0)	
LC50 - Fish [1]	7.45 mg/L (species: Oncorhynchus mykiss- Exposure time :96h)
Sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	45.4mg/L (Exposure time: 96h – species: Oncorhynchus mykiss [static])
EC50-Crustacea [1]	40 mg/L
Persistence/Degradability	Not established.
Bioaccumulation potential	Not established.
Sodium chloride (7647-14-5)	
BCF Fish 1	(no bioaccumulation)
Mobility in soil	No additional information available
Other Adverse Effects	Avoid release to the environment.
Section 13: Disposal Considerations	
Waste treatment methods	
Waste Disposal Recommendations	Dispose of contents/container in accordance with local/regional/national/territorial/provincial, and international regulations
Ecology-Waste materials	Avoid release to the environment
Section 14: Transport Information	
Department of Transportation (DOT)	
In accordance with DOT – Not regulated	
In accordance with IMDG – Not regulated	



In accordance with IATA – Not regulated

In accordance with TDG – Not regulated

Section 15: Regulatory Information

US State regulations

Hydrochloric acid (7647-01-0)	U.S. – New jersey- Right To Know Hazardous substance List
	U.S. - Pennsylvania - RTK (Right to Know) List
	U.S. - Massachusetts - Right To Know List
	U.S. - Pennsylvania - RTK (Right to Know) -Environmental Hazard List
Sodium hydroxide (1310-73-2)	U.S. – New jersey- Right To Know Hazardous substance List
	U.S. - Pennsylvania - RTK (Right to Know) List
	U.S. - Massachusetts - Right To Know List
	U.S. - Pennsylvania - RTK (Right to Know) -Environmental Hazard List

Section 16: Other Information

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Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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