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Product Name	**Plerixafor Injection 24 mg/1.2 mL (20 mg/mL)**	

1. Product Information

Product Name : Plerixafor Injection
Strength : 24 mg/1.2 mL (20 mg/mL)

2.Information on Active

C.A.S. No : : 110078-46-1

Molecular Formula : $C_{28}H_{54}N_8$

Molecular Weight : 502.78 g/mol

Chemical Name : 1, 1'-[1,4-phenylenebis (methylene)]-bis-1,4,8,11- tetraazacyclotetradecane

3. Hazards Identification

Precautionary Statements:

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, colorless to pale yellow liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation: No data available.

Eye: No data available.

Skin: No data available.

Ingestion: Plerixafor free base is not absorbed orally.

Chronic Effects: No data available.

Target Organs: Plerixafor, free base: Blood, reproductive outcomes, bone, liver, and spleen.

Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

Potential Environmental Effects:

Unknown.

4. First Aid Measures

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. Fire Fighting Measures

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Not applicable

Specific Hazards Arising from the Chemical:

None known.

Standard Protective Equipment and Precautions for Firefighters:

As in any fire, firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. Accidental Release Measures

Personal Precautions:

Wear Personal Protective Equipment (PPE). Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

No information available.

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations.

7. Handling and Storage

Handling:

Follow good laboratory hygiene practices, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at room temperature. Keep container tightly closed. Do not store with incompatible substances.

8. Exposure Controls/Personal Protection

Exposure Guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

The occupational exposure limit (OEL) for Plerixafor Injection 24 mg/1.2 mL (20 mg/mL) is 3 $\mu g/m^3$ as an 8-hour TWA. The OEL of Plerixafor Injection 24 mg/1.2 mL (20 mg/mL) is based upon the best scientific information available at this time.

Engineering Controls:

This preparation is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory: A respirator is not required under normal conditions of use.

Eye/Face: Wear appropriate protective chemical safety glasses.

Skin: Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Gloves: Wear chemical resistant protective gloves.

General: Follow company-specific safety procedures.

9. Physical and Chemical Properties

Appearance: Clear, colorless to pale yellow liquid.

PH: 6.0 – 7.5.

Odor: Unknown.

Solubility: Water-soluble.

Boiling Point: Not available.

Vapor Pressure: Not available.

Melting Point: Not applicable.

Partition Coefficient (n-octanol/water): Not available.

Freezing Point: Not available.

Vapor Density: Not available.

Flammability/Explosivity Limits in Air, Lower: Not available.

Flammability/Explosivity Limits in Air, Upper: Not available.

Auto-Ignition Temperature: Not available.

Flash Point: Not available.

10. Stability and Reactivity

Chemical Stability:

Stable under ordinary conditions of use and storage.

Incompatible Materials:

Unknown.

Hazardous Decomposition Products:

Unknown.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. Toxicological Information

Effects of Exposure:

Plerixafor is a potent and selective antagonist of the CXCR4 chemokine receptor and blocks binding of its

cognate ligand, stromal cell-derived factor-1alpha. It is under investigation for the mobilization of stem cells prior to high dose chemotherapy in the treatment of multiple myeloma, non-Hodgkin's lymphoma, and other hematopoietic malignancies. Concurrently, Plerixafor is under investigation for the mobilization of stem cells in the treatment of acute myocardial infarction.

Acute Effects:

Acute overexposure through subcutaneous (SC) or intravenous (IV) injection may cause increased heart rate, central nervous system effects, and GI upset and parathesia.

For Plerixafor, free base:

LD50 mouse, SC: 16.3 mg/kg

LD50 rat, SC: >50 mg/kg

LD50 mouse and rat, IV injection: 5.2 mg/kg

Chronic Effects:

No data available.

Carcinogenicity:

Not listed by ACGIH, IARC, NIOSH, NTP OR OSHA. No carcinogenicity studies have been performed.

Mutagenicity:

For Plerixafor, free base:

Negative genotoxicity testing (Ames, chromosomal aberration test with CHO cells, and rat micronucleus test).

Teratogenicity:

No data available.

Reproductive Effects:

For Plerixafor, free base:

Adverse fetal effects were observed in pregnant rats following subcutaneous injection. Fertility studies with this material have not been conducted. The effect on pregnant woman due to occupational exposure to this material is unknown.

Sensitization:

No data available.

12. Ecological Information

Ecotoxicity:

No data available.

Persistance and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. Disposal Considerations

Methods of Disposal:

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Unused supplies of investigational drugs must be returned to the dispensing pharmacy. Pharmacists shall return the unused drug or obtain authorization for alternative disposal in accordance with U.S. FDA regulations (21 CFR 312.59).

14. Transport Information

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

Per U.S. FDA regulations, 21 CFR 312.6(a): The immediate package of an investigational new drug intended for human use shall bear a label with the statement: "CAUTION: New drug limited by Federal (or United States) law to investigational use."

15. Regulatory Information

US Federal Regulations:

This pharmaceutical preparation is regulated by the U.S. FDA. Caution: New drug limited by Federal (or United States) law to investigational use.

International Regulations:

This preparation is intended for use as a medicinal product. If approved for use in the EU, it is regulated under the Medicinal Products Directive (2001/83/EC) and is exempt from classification under the Dangerous Substances Directive (67/548/EC).

Canadian Hazardous Products:

WHMIS Status: Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class: Exempt

Risk Phrases: None

Safety Phrases: None

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.