

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Plerixafor Injection

### 1.2. Intended Use of the Product

Hematopoietic stem cell mobilizer indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma.

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

### 1.4. Emergency Telephone Number

**Emergency Number** : VelocityEHS

(800)255-3924 (North America)

+1 (813)248-0585 (International)

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

#### GHS-US/CA Classification

Reproductive toxicity Category 2

H361

### 2.2. Label Elements

#### GHS-US/CA Labeling

**Hazard Pictograms (GHS-US/CA)** :



GHS08

**Signal Word (GHS-US/CA)**

: Warning

**Hazard Statements (GHS-US/CA)**

: H361 - Suspected of damaging fertility or the unborn child.

**Precautionary Statements (GHS-US/CA)**

: 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, and 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.

### 2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

### 2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

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### 3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	water / AQUA	(CAS-No.) 7732-18-5	97.51	Not classified
Plerixafor	-	(CAS-No.) 110078-46-1	2	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Repr. 2, H361
Sodium chloride	Salt / SEA SALT / Sodium salt of hydrochloric acid / SODIUM CHLORIDE / Sodium chloride (NaCl) / Sea salt	(CAS-No.) 7647-14-5	0.49	Not classified
Hydrochloric acid	HYDROCHLORIC ACID / Hydrochloric acid, anhydrous / Muriatic acid / Hydrogen chloride / hydrochloric acid	(CAS-No.) 7647-01-0	0.0001	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
Sodium hydroxide	SODIUM HYDROXIDE / Sodium hydroxide (Na(OH)) / Caustic soda / LYE	(CAS-No.) 1310-73-2	0.0001	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 1, H370 Aquatic Acute 3, H402
Nitrogen	Nitrogen gas / Nitrogen, liquefied / NITROGEN / Nitrogen, compressed / nitrogen	(CAS-No.) 7727-37-9	0.0001	Press. Gas (Ref. Liq.), H281 Simple Asphy

Full text of H-statements: see section 16

\*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of 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).

**Inhalation:** When symptoms occur: 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.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**General:** Suspected of damaging fertility or the unborn child.

**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.

### 4.3. 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

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing media suitable for surrounding type of fire.

**Unsuitable Extinguishing Media:** None known.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not flammable.

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**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon oxides, Nitrogen oxides.

### 5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray.

#### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup 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 soon as conditions permit. Ventilate area.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials 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.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do not breathe vapors, spray, mist.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

**Storage Temperature:** 25 °C (77°F); excursions permitted to 15°C–30°C (59°F–86°F).

### 7.3. Specific End Use(s)

Hematopoietic stem cell mobilizer indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen

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USA OSHA	OSHA PEL (Ceiling)	7 mg/m <sup>3</sup>
USA OSHA	OSHA PEL C [ppm]	5 ppm
USA NIOSH	NIOSH REL (Ceiling)	7 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL C [ppm]	5 ppm
USA IDLH	IDLH [ppm]	50 ppm
Alberta	OEL C	3 mg/m <sup>3</sup>
Alberta	OEL Ceiling [ppm]	2 ppm
British Columbia	OEL Ceiling [ppm]	2 ppm
Manitoba	OEL Ceiling [ppm]	2 ppm
New Brunswick	OEL C	7.5 mg/m <sup>3</sup>
New Brunswick	OEL Ceiling [ppm]	5 ppm
Newfoundland & Labrador	OEL Ceiling [ppm]	2 ppm
Nova Scotia	OEL Ceiling [ppm]	2 ppm
Nunavut	OEL Ceiling [ppm]	2 ppm
Northwest Territories	OEL Ceiling [ppm]	2 ppm
Ontario	OEL Ceiling [ppm]	2 ppm
Prince Edward Island	OEL Ceiling [ppm]	2 ppm
Québec	Plafond (OEL Ceiling) [ppm]	2 ppm
Saskatchewan	OEL Ceiling [ppm]	2 ppm
Yukon	OEL C	7 mg/m <sup>3</sup>
Yukon	OEL Ceiling [ppm]	5 ppm
<b>Sodium hydroxide (1310-73-2)</b>		
USA ACGIH	ACGIH OEL Ceiling	2 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) [1]	2 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (Ceiling)	2 mg/m <sup>3</sup>
USA IDLH	IDLH	10 mg/m <sup>3</sup>
Alberta	OEL C	2 mg/m <sup>3</sup>
British Columbia	OEL C	2 mg/m <sup>3</sup>
Manitoba	OEL C	2 mg/m <sup>3</sup>
New Brunswick	OEL C	2 mg/m <sup>3</sup>
Newfoundland & Labrador	OEL C	2 mg/m <sup>3</sup>
Nova Scotia	OEL C	2 mg/m <sup>3</sup>
Nunavut	OEL C	2 mg/m <sup>3</sup>
Northwest Territories	OEL C	2 mg/m <sup>3</sup>
Ontario	OEL C	2 mg/m <sup>3</sup>
Prince Edward Island	OEL C	2 mg/m <sup>3</sup>
Québec	Plafond (OEL Ceiling)	2 mg/m <sup>3</sup>
Saskatchewan	OEL C	2 mg/m <sup>3</sup>
Yukon	OEL C	2 mg/m <sup>3</sup>
<b>Nitrogen (7727-37-9)</b>		
USA ACGIH	ACGIH chemical category	Simple asphyxiant See Appendix F: Minimal Oxygen Content

## 8.2. Exposure Controls

**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.

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**Eye and Face Protection:** Chemical safety goggles.

**Skin and Body Protection:** Wear suitable protective clothing.

**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

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, colorless to pale yellow aqueous solution.
Odor	: No data available
Odor Threshold	: No data available
pH	: 6 – 7.5
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

### 10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

### 10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

### 10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

### 10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides, Nitrogen oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects - Product

**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

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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 Contact:** Prolonged exposure may cause skin irritation.

**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.

### 11.2. Information on Toxicological Effects - Ingredient(s)

#### LD50 and LC50 Data:

<b>Sodium chloride (7647-14-5)</b>	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 mg/L (Exposure time: 1 h)
<b>Hydrochloric acid (7647-01-0)</b>	
LD50 Dermal Rabbit	> 5010 mg/kg
<b>Sodium hydroxide (1310-73-2)</b>	
LD50 Oral Rat	325 mg/kg
<b>Hydrochloric acid (7647-01-0)</b>	
IARC Group	3

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General:** Not classified.

<b>Sodium chloride (7647-14-5)</b>	
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)
<b>Hydrochloric acid (7647-01-0)</b>	
LC50 Fish 1	7.45 mg/L (Species: Oncorhynchus mykiss - Exposure time: 96h)
<b>Sodium hydroxide (1310-73-2)</b>	
LC50 Fish 1	45.4 mg/L (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/L

### 12.2. Persistence and Degradability

<b>Plerixafor Injection</b>	
Persistence and Degradability	Not established.

### 12.3. Bioaccumulative Potential

<b>Plerixafor Injection</b>	
Bioaccumulative Potential	Not established.
<b>Sodium chloride (7647-14-5)</b>	
BCF Fish 1	(no bioaccumulation)

### 12.4. Mobility in Soil

No additional information available

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## 12.5. Other Adverse Effects

**Other Information:** Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. 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

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

### 14.1. In Accordance with DOT

Not regulated for transport

### 14.2. In Accordance with IMDG

Not regulated for transport

### 14.3. In Accordance with IATA

Not regulated for transport

### 14.4. In Accordance with TDG

Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

<b>Plerixafor Injection</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Health hazard - Reproductive toxicity
<b>Sodium chloride (7647-14-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
<b>Hydrochloric acid (7647-01-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
<b>CERCLA RQ</b>	5000 lb
<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	500 lb (gas only)
<b>SARA Section 313 - Emission Reporting</b>	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
<b>Sodium hydroxide (1310-73-2)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
<b>CERCLA RQ</b>	1000 lb
<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
<b>Nitrogen (7727-37-9)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

### 15.2. US State Regulations

<b>Hydrochloric acid (7647-01-0)</b>
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
<b>Sodium hydroxide (1310-73-2)</b>
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
<b>Nitrogen (7727-37-9)</b>

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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

### 15.3. Canadian Regulations

#### Sodium chloride (7647-14-5)

Listed on the Canadian DSL (Domestic Substances List)

#### Hydrochloric acid (7647-01-0)

Listed on the Canadian DSL (Domestic Substances List)

#### Sodium hydroxide (1310-73-2)

Listed on the Canadian DSL (Domestic Substances List)

#### Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

#### Nitrogen (7727-37-9)

Listed on the Canadian DSL (Domestic Substances List)

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

**Date of Preparation or Latest Revision** : 05/23/2023

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

### GHS Full Text Phrases:

H281	Contains refrigerated gas; may cause cryogenic burns or injury
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H370	Causes damage to organs
H401	Toxic to aquatic life
H402	Harmful to aquatic life

**NFPA Health Hazard** : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

**NFPA Fire Hazard** : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

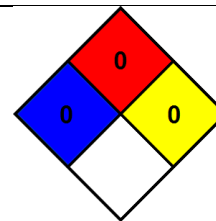
**NFPA Reactivity Hazard** : 0 - Material that in themselves are normally stable, even under fire conditions.

### HMIS III Rating

**Health** : 0 Minimal Hazard - No significant risk to health  
\* Chronic - Chronic (long-term) health effects may result from repeated overexposure

**Flammability** : 0 Minimal Hazard

**Physical** : 0 Minimal Hazard



*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*