



## Safety Data Sheet

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### Section 1 – Identification

Trade name: IXINITY™ (Recombinant - Bulk Drug Substance)

Common Name: IXINITY™ (Recombinant - Bulk Drug Substance)

Synonym(s): Human coagulation factor IX (Recombinant), Christmas factor, plasma thromboplastin factor, trenonacog alfa

Family: N/A

Details of the supplier of the safety data sheet

### **Distribution Information**

#### **Supplier**

Aptevo Biotherapeutics LLC  
920 Cassatt Road, Suite 100  
Berwyn PA 19312  
Tel: +1-888-616-0855  
Fax: +1-888-616-0856

Emergency Phone # 204-275-4178

### Section 2 - Hazard(s) identification

GHS Classification

Skin irritation (Category 3)

Eye irritation (Category 2B)

Hazard statement(s)

H316 : Causes mild skin irritation

H320 : Causes eye irritation

Precautionary statement(s)

P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

#### **Potential Health Effects**

Eyes : May cause eye irritation

Skin : May be harmful if absorbed through skin. May cause skin irritation.

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- Inhalation : May be harmful if inhaled. May cause respiratory tract irritation.
- Ingestion : May cause irritation of the digestive tract.
- Target Organ(s) : Blood system

### Section 3 - Composition/information

Common Name	CAS #	Concentration
Coagulation Factor IX	1232401-60-3	100 – 300 IU/mL
Histidine	7006-35-1	1.55 mg/mL
Mannitol	69-65-8	30.0 mg/mL
Trehalose Dihydrate	99-20-7	10.0 mg/mL
Sodium Chloride	7647-14-5	3.86 mg/mL
Polysorbate 80	9005-65-6	0.075 mg/mL

### Section 4 - First-aid measures

- Eye Contact : Rinse thoroughly with plenty of water for at least 15 minutes and seek medical advice.
- Skin Contact : Remove contaminated clothing and wash off immediately with soap and plenty of water. If symptoms persist, contact a physician.
- Inhalation : Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, contact a physician.
- Ingestion : Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. If symptoms persist, contact a physician.

### Section 5 - Fire-fighting measures

Flash Point: N/A  
 Flammable Limits: N/A  
 Fire Extinguishing Media: N/A  
 Special Fire-Fighting Procedure: N/A  
 Unusual Fire and Explosion Hazards: N/A

### Section 6 - Accidental release measures

- Personal Precautions : Use protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.

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- Environmental Precautions : Prevent product from entering drains.
- Methods of Containment : Soak up with inert absorbent material and dispose of as hazardous  
and Clean-up waste. Keep in suitable, closed containers for disposal.

### Section 7- Handling and Storage

- Precautions for Safe Handling : Avoid contact with skin and eyes. Avoid formation of aerosols. Provide appropriate exhaust ventilation at places where aerosols is formed. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

- Conditions for Safe Storage : Store in a cool place and protect from light. Use a tightly closed container.

### Section 8 - Exposure controls/personal protection

#### **Individual Protection Measures**

- Respiratory Protection : No protective respiratory equipment is typically required. Where exposure limits are exceeded or if irritation or other symptoms are experienced, follow the OSHA respirator regulations found in 29 CFR 1910.134 and use a NIOSH/MSHA approved respirator.
- Hand Protection : Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
- Skin and Body Protection : Impervious clothing. The type of protective clothing must be selected in accordance to the concentration and amount of material being handled.

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Eye / Face Protection	:	Handle with protective goggles and faceshield where risk of splash to the eyes or face.
General Hygiene	:	Handle in accordance with good industrial hygiene and safety
Considerations	:	practice. When in use, do not eat, drink or smoke. Wash hands before breaks and at end the workday.

### Section 9 – Physical and chemical properties

Boiling Point: N/A                      Vapor Density: N/A  
 Vapor Pressure: N/A                    Solubility in Water: N/A  
 Melting Point: N/A                    Evaporation Rate: N/A  
 Specific Gravity (H<sub>2</sub>O=1) N/A Appearance and Color: clear, transparent, faint yellow

Physical State	:	Liquid
Color	:	Clear, colorless
Odor	:	no data available
Odor Threshold	:	no data available
pH	:	6.8 ± 0.3
Specific Gravity	:	no data available
Water Solubility	:	no data available
Water Solubility	:	no data available
Evaporation Rate	:	no data available
Partial Coefficient (n-octanol/water)	:	no data available
Density	:	no data available
Vapor Pressure	:	no data available
Relative Vapor Density	:	no data available
Boiling Point	:	no data available
Autoignition Temperature	:	no data available
Melting Point	:	no data available
Flash Point	:	no data available
Lower Explosion Limit	:	no data available
Upper Explosion Limit	:	no data available
Auto-ignition Temperature	:	no data available
Decomposition Temperature	:	no data available
Viscosity	:	no data available

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### Section 10 - Stability and reactivity

Stability: Product is stable.

Incompatibility: N/A

Hazardous Decomposition of By-products: N/A

Hazardous Polymerisation: N/A

### Section 11. Toxicological information

LD50 Oral	:	No data available.
LC50 Inhalation	:	No data available.
LD50 Dermal	:	No data available.
Skin Corrosion/Irritation	:	No data available.
Serious Eye Damage /Irritation	:	No data available.
Respiratory or Skin Sensitization	:	No data available.
Other information on acute toxicity	:	No data available.

### Section 12 - Ecological information

Toxicity	:	No data available.
Persistence and Degradability	:	No data available.
Bioaccumulative Potential	:	No data available.
Mobility in Soil	:	No data available.
Other Adverse Effects	:	No data available.

### Section 13 - Disposal considerations

Dispose of in accordance with local, state and federal regulations.

### Section 14 - Transport information

According to DOT and IATA regulations this material is considered a biologic product and should be shipped accordingly.

### Section 15 - Regulatory information

N/A

### Section 16 - Other information

This information is being furnished to comply with the United States Occupational Safety and Health Act (OSHA) and its regulations, and other federal, state and local laws. This document is intended as a guideline to the appropriate precautionary handling of the material by a person



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trained in handling these materials. The information herein is believed by Aptevo to be correct to the best of its knowledge. However, the handler of this material is responsible for determining the precautions and dangers associated with the material. Newly discovered hazards are frequent, and this information may not be completely up to date.

Aptevo makes no warranty expressed or implied with regard to the information provided in the SDS.

If you have any questions contact Aptevo Biotherapeutics for further information.