



MATERIAL SAFETY DATA SHEET

BAYER HEALTHCARE LLC
Biological Products Division
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TRANSPORTATION EMERGENCY
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INTERNATIONAL : (703) 527-3887

NON-TRANSPORTATION
BAYER EMERGENCY PHONE : (800) 288-8371
BAYER INFORMATION PHONE: (800) 662-2927

Section 1: Product and Company Identification

Product Name: Kogenate - FS
Material Number: 8612016
Common/Generic Name: Coagulation Factor VIII
Chemical Family: Lyophilized Human Protein
NDC Number: None.

Section 2: Composition/Information on Ingredients

HAZARDOUS INGREDIENTS

<u>Ingredient Name/</u>	<u>Exposure Limits</u>	<u>Concentration</u>	
<u>CAS Number</u>		<u>Min.</u>	<u>Max.</u>
This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.			

Section 3: Hazards Identification

EMERGENCY OVERVIEW

Color: White **Form:** Solid Powder **Odor:** Odorless
Product poses little or no hazard if spilled and no unusual hazard if involved in a fire.

POTENTIAL HEALTH EFFECTS

Route(s) of Entry: Accidental., Skin Contact, Eye Contact, Ingestion, Appropriate route of entry., Intravenous

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

General Effects of Exposure

Acute Effects of Exposure: Acute overexposure to this product may cause thrombosis.

Chronic Effects of Exposure: Chronic overexposure to this product may cause inhibitor formation.

Carcinogenic Components:

NTP: None

IARC: None

OSHA: None

Medical Conditions Aggravated by Exposure: Liver disorders

Section 4: First Aid Measures

First Aid for Eye: In case of contact, flush with plenty of water for at least 15 minutes. Call a physician.

First Aid for Skin: In case of skin contact, wash affected areas with soap and water. Contact a physician if irritation develops. Immediately remove contaminated clothing and shoes. Wash clothing and shoes before reuse.

First Aid for Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

First Aid for Ingestion: Contact poison control center or 1-800-288-8371.

Section 5: Fire Fighting Measures

Flash Point: Not Established

Flammable Limits:

Upper Explosion Limit (UEL %): Not Established

Lower Explosion Limit (LEL %): Not Established

Auto-ignition Temperature: Not Established

Extinguishing Media:

Suitable: Water, Dry Chemical, Carbon Dioxide, Foam

Special Fire Fighting Procedures: Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

Section 6: Accidental Release Measures

Spill or Leak Procedures: Use appropriate personal protective equipment during clean up. Prevent from entering open drains and waterways. Contact with 1% sodium hypochlorite for 1 hour and put to a sanitary sewer with water. Avoid creating dusty conditions.

Section 7: Handling and Storage

Storage Temperature:

Minimum: 35 °F (2 °C)

Maximum: 46 °F (8 °C)

Shelf Life: Do not use after expiration date.

Special Sensitivity: Avoid freezing as breakage of the container might occur.

Handling/Storage Precautions: Store in a dry place away from excessive heat. Containers should be kept tightly closed to prevent contamination. Use normal precautions for storage of a drug. Avoid contact with eyes. Avoid contact with skin or clothing. Wash thoroughly after handling. Follow necessary handling and storage procedures in compliance with the bloodborne pathogen standard under 29CFR1910.1030().

Section 8: Exposure Controls/Personal Protection

Personal Protection Equipment

Eye Protection Requirements: Chemical safety goggles or glasses.

Skin Protection Requirements: Lab coat., Employees should wash their hands and face before eating, drinking or using tobacco products., Gloves, long sleeved shirts and pants.

Ventilation Requirements: Under normal conditions of use, special ventilation is not required.

Respirator Requirements: A NIOSH approved dust respirator should be worn if inhalation of dust is a problem.

Work Practices: Normal clinical practice and in compliance with the bloodborne pathogen standard under 29CFR1910.1030.

Additional Protective Measures: Emergency showers and eye wash stations should be available. Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

Section 9: Physical and Chemical Properties

Physical Form: Solid
Appearance: Powder
Color: White

Odor: Odorless
pH: Not Applicable
Boiling Point: Not Established
Melting/Freezing Point: Not Established
Viscosity: Not Established
Solubility in Water: Soluble
Specific Gravity: 1.01
Bulk Density: Not Established
Vapor Pressure: Not Established

Section 10: Stability and Reactivity

Stability: Stable
Hazardous Polymerization: Will not occur
Substances to Avoid: Oxidizing agents, Reducing agents
Conditions to Avoid: None known.
Decomposition Products: None known.

Section 11: Toxicological Information

Toxicity Data for Kogenate - FS

Toxicity Note: No data available for this product.

Section 12: Ecological Information

Ecological Data for Kogenate - FS

Ecological Note: No data available for this product.

Section 13: Disposal Considerations

Waste Disposal Method: Place in containers and incinerate in accordance with existing federal, state and local environmental regulations.

Section 14: Transportation Information

Technical shipping name: Human plasma proteins

Domestic Surface Transportation (DOT)

Hazard Class or Division: Non-Regulated

Marine Transportation (IMO / IMDG)

Hazard Class Division Non-Regulated

Number:

Air Transportation (ICAO / IATA)

Hazard Class Division Non-Regulated

Number:

Section 15: Regulatory Information

United States Federal Regulations

OSHA Hazcom Standard Not subject to OSHA
Rating:

TSCA Inventory List: **This product is exempt from TSCA Regulation under Section 3 (2)(B)(vi) when used for pharmaceutical application.**

CERCLA Hazardous Substance:

Component(s)
None

Reportable Quantity

SARA Title III

SARA Section 302 Extremely Hazardous Substances:

Component(s)/
CAS Number
Exempt

Concentration
Min. Max.

SARA Section 311/312 Hazard Categories: Non-hazardous under Section 311/312

SARA Section 313 Toxic Chemicals:

Component(s)/
CAS Number
Exempt

Reporting
Threshold

Concentration
Min. Max.

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

State Right-to-Know Information

Component(s)/
CAS Number

State Code

Concentration
Min. Max.

State Code Translation Table

Section 16: Other Information

HMIS Rating

Health		0
Flammability		0
Reactivity		0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe
*=Chronic Health Hazard

BAYER HEALTHCARE LLC's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS and NFPA ratings are provided by BAYER HEALTHCARE LLC as a customer service.

Contact: John Parrish
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MSDS Number: R37182
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