



SAFETY DATA SHEET

122000001143

Kogenate® - FS / PF / N

Version 2.0

Revision Date 05/15/2014

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**Product information**

Product Name: Kogenate® - FS / PF / N
Generic name: Coagulation Factor VIII
MSDS Number: 122000001143

Use : unfinished drug mixture

Company

BAYER HEALTHCARE LLC
Biological Products Division
555 White Plains Road
Tarrytown, NY 10591-5097
USA
(800) 662-2927

Chemtrec: (800) 424-9300

2. HAZARDS IDENTIFICATION**Emergency Overview**

Colour: white **Form:** solid, powder **Odour:** odourless.

Product poses little or no hazard if spilled and no unusual hazard if involved in a fire. Appropriate route of entry: intravenous Accidental: Skin contact Eye contact Ingestion

GHS Classification:

Not a dangerous substance / mixture according to GHS.

GHS Label element:

Not a dangerous substance / mixture according to GHS.

Other hazards which do not result in classification:

None known.

Hazard Communication (29CFR 1910.1200)

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This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

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

**Medical Conditions Aggravated by
Exposure**

Liver disorders

3. COMPOSITION/INFORMATION ON INGREDIENTS

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

Label Ingredients: Water; Sucrose; Sodium glycinate; Sodium Chloride; Lysine
hydrochloride;

Other Ingredients

Weight percent
5%

Components
Octocog - alpha

CAS-No.

4. FIRST AID MEASURES

If inhaled: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

In case of skin contact: In case of skin contact, wash affected areas with soap and water. Take off contaminated clothing and shoes immediately. Wash clothing and shoes before reuse. Contact a physician if irritation develops.

In case of eye contact: In case of contact, flush with copious amounts of water for at least 15 minutes. Call a physician.

If swallowed: In case of accidental ingestion, contact your regional poison center or physician immediately.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water, Dry chemical, Carbon dioxide (CO₂), Foam

Specific hazards during firefighting: Fire may cause evolution of: Carbon monoxide (CO)
Carbon dioxide (CO₂)

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for cleaning up: Place in closed containers. Label for proper disposal.

Use appropriate personal protective equipment during clean up. Prevent from entering open drains and waterways. Avoid creating dusty conditions.

Additional advice: Avoid dust formation.

Further Accidental Release Notes Avoid dust formation.

7. HANDLING AND STORAGE

Handling:

Store in a dry place away from excessive heat. Use normal precautions for storage of a drug. Containers should be kept tightly closed to prevent contamination. Avoid contact with eyes. Avoid excessive contact with skin or clothing. Wash ... thoroughly after handling.

No special protective measures against fire required.

Storage:

For storage suitable stores with adequate product-reception volume must be used. During handling local official regulations must be observed in order to avert impairment of water by the product.

Storage temperature: 35.6 - 46.4 °F (2 - 8 °C)
Do not use after expiration date. Do not freeze.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory protection:

No personal respiratory protective equipment normally required. Breathing apparatus only if aerosol or dust is formed. Effective dust mask.

Recommended Filter type: HEPA

Hand protection:

Chemically resistant gloves.

Eye protection:

Safety glasses

Other protective measures:

No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients.

For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.

Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	solid, powder
Colour:	white
Odour:	odourless
Odour Threshold:	No applicable information is available
Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	No applicable information is available
Bulk density:	No applicable information is available
Vapour pressure:	Not applicable
Viscosity, dynamic:	No applicable information is available
Viscosity, kinematic:	No applicable information is available
Flow time:	No applicable information is available
Surface tension:	No applicable information is available
Miscibility with water:	No applicable information is available
Water solubility:	Product is highly soluble.
pH:	No applicable information is available
Relative density:	1.01
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	No applicable information is available
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

10. STABILITY AND REACTIVITY

Conditions to avoid: no data available

Materials to avoid: Oxidizing agents, Reducing agents

Hazardous reactions: None known. Stable

Thermal decomposition:

no data available

Hazardous decomposition products:

Carbon monoxide (CO), Carbon dioxide (CO₂)

11. TOXICOLOGICAL INFORMATION

Toxicity Prenote

There is no data available for this product.

Pharmaceutic effects:

anticoagulant human clotting factor

Carcinogenicity:

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

STOT - single exposure:

no data available

STOT - repeated exposure:

no data available

12. ECOLOGICAL INFORMATION

General advice:

Do not allow to enter surface waters or groundwater.

13. DISPOSAL CONSIDERATIONS

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

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14. TRANSPORT INFORMATION

Land transport (CFR)

Non-Regulated

US Sea transport (IMDG)

Non-Regulated

US Air transport (ICAO / IATA cargo aircraft only)

Non-Regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)

Non-Regulated

International IATA

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IMDG

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15. REGULATORY INFORMATION

Other regulations: No statements available.

US. Toxic Substances Control Act This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A) Components

None

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

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required Components

None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components

None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
15 - 40%	Sucrose / Sugar	57-50-1

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Non-Hazardous

16. OTHER INFORMATION

HMIS Rating

Health	0
Flammability	0
Physical Hazard	0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

* = Chronic Health Hazard

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.