

1. PRODUCT AND MANUFACTURER (see section 16) IDENTIFICATION

Product Name: Helixate® FS

Distributor: CSL Behring L.L.C.
Address: 1020 First Avenue
 PO Box 61501
 King of Prussia, PA 19406-0901

Telephone Number: (610) 878-4000
Emergency Product Information: (800) 504-5434
Emergency Response (800) 424-9300

This is a biological product with specific therapeutic activity. It is manufactured and offered for sale under registration and approval of the U.S. Food and Drug Administration. The U.S. OSHA does not require MSDSs for biological hazards. CSL Behring provides this information as a service to customers and others who might handle or otherwise come in contact with this product.

2. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Common Name</u>	<u>CAS No.</u>	<u>Comments</u>
Antihemophilic Factor (Recombinant) Others, when reconstituted to dose-form	NA	Active ingredient
Sucrose, USP (0.9-1.3%)	57-50-1	Stabilizer
Calcium Chloride, USP (2-3 mM)	10043-52-4	Osmotic balance adjustment
Sodium (27-36 mEq/L) Chloride (32-40 mEq/L)		Osmotic balance adjustment Osmotic balance adjustment
Glycine, USP (21-25 mg/mL)	56-40-6	Stabilizer
Histidine, USP (18-23mM)	7006-35-1	Stabilizer
Imidazole (≤20 ug/1000 IU AHF)	288-32-4	Stabilizer
Polysorbate-80 (≤ 35 ug/mL)	9005-65-6	Stabilizer
Tri-n-butylphosphate (≤ 5 ug/1000 IU AHF)		
Copper (≤0.6 ug/1000 IU AHF)		
Water For Injection, USP	7732-18-5	Volume adjustment

3. HAZARDS IDENTIFICATION

Potential Health Effects

This product is a highly purified glycoprotein that has been manufactured with recombinant DNA technology by a genetically engineered Baby Hamster Kidney (BHK) cell line. The product undergoes a minimum of two different virus reduction procedures. However, the risk of infectivity due to known or as yet unknown pathogens cannot be totally eliminated from this product.

No adverse health effects anticipated with normal handling and use in appropriate medical setting. Medical implications of therapeutic use are described in product package insert or may be found in the Physicians' Desk Reference. Individuals with known hypersensitivity to mouse or hamster protein or to other constituents of the preparation may experience an allergic type reaction if significantly exposed to the product.

Emergency Overview:

This product is a sterile prescription pharmaceutical. It is to be administered only at the order of a licensed physician. This product is safe when used for its intended purpose and administered as directed by a physician. In addition, no adverse health effects are anticipated as a result of incidental contact or exposure to this product by those handling it or administering it in a therapeutic setting. More detailed information is available in the product package insert. Please report adverse events in patients using this product to the manufacturer at the telephone number listed Section 1 or Section 16.

Eye

No data. No adverse health effects reported nor anticipated.

Skin Contact

No data. No adverse health effects reported nor anticipated.

Skin Absorption

This product is not absorbed through the skin.

Ingestion

Not intended for oral use. Relatively non-toxic if ingested.

Chronic Effects/Carcinogenicity

None known or anticipated under normal handling and exposure conditions.

4. FIRST AID MEASURES**Eyes**

Flush with water for 15-20 minutes. If irritation develops, seek medical attention.

Skin

Wash with soap and water. If irritation or other symptoms develop, seek medical attention.

Ingestion

Rinse from mouth and seek medical guidance. Induce vomiting only as directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation

If inhaled, remove to fresh air. Seek medical attention if symptoms develop or if breathing is difficult.

5. FIRE FIGHTING MEASURES**FLAMMABILITY**

Flash Point: NA

Flammable Limits in Air-Lower: NA

Flammable Limits in Air-Upper: NA

Auto-Ignition Temperature: NA

General Hazards

Product is not flammable. The only potential fire hazard would involve packaging material.

Fire Fighting Extinguishing Media

Packaging material fires may be extinguished with water, carbon dioxide, or dry chemical.

Fire Fighting Instructions

Fire fighting personnel should respond with appropriate protective clothing, firefighting gear, and breathing equipment as trained. All other personnel should exit the area and proceed to a gathering point in an area unaffected by the fire and smoke.

Hazardous Combustion Products

Packaging material fire may produce carbon monoxide and other gaseous asphyxiants plus airborne particulate matter.

6. ACCIDENTAL RELEASE MEASURES

Large Spill

Absorb spills with material suitable for aqueous solutions and dispose in solid waste container, or mop spilled material with detergent/water or bleach/water solution and dispose in sanitary sewer. Ventilate area, if desired.

Small Spill

Clean area of spill with wetted toweling and dispose in solid waste container, or follow procedure for large spills.

7. HANDLING AND STORAGE

Special Handling

Prevent physical damage to package to avoid breakage and spilling.

Special Storage

Store in accordance with the conditions specified in the product package insert.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eye Protection

None required for protection against the product. Eye protection may be required by procedure of administration.

Skin Protection

None required for protection against the product. Medical-grade examination or surgical gloves may be required by procedure of administration.

Respiratory Protection

None required.

Engineering Controls

Not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form of Pure Concentrate Stable, white to off-white powder (lyophilized)

As reconstituted:

Physical Form:	Clear aqueous solution
Color:	Colorless to faint yellow
Odor:	Unspecified
Boiling Point:	Unspecified
Melting Point:	Unspecified
Freezing Point:	Unspecified
pH:	6.9 ± 0.5
Solubility in Water:	Complete
Specific Gravity:	Unspecified
Decomposition Temperature:	Unspecified
Odor Threshold:	Unspecified
Evaporation Rate:	Unspecified
Vapor Pressure:	Unspecified
Vapor Density:	Unspecified

10. STABILITY AND REACTIVITY**Stability**

Stable for period indicated on the label when stored at conditions specified in product package insert.

Incompatibility

No known incompatibilities.

Hazardous Decomposition Products

No known hazardous decomposition products.

Hazardous Polymerization

Hazardous polymerization will not occur.

General Information

No additional information.

11. TOXICOLOGICAL INFORMATION**Toxicology Text**

The pure, lyophilized concentrate of Helixate® FS is a sterile, stable, purified, non-pyrogenic, dried powder with biological activity indicated in the treatment of Hemophilia A. When reconstituted into its dose-form for intravenous administration, this product is a sterile, aqueous solution containing recombinant antihemophilic factor, stabilizers, and osmotic agents. It also contains trace amounts of mouse and hamster protein used in the process of manufacturing and purifying the concentrate. It is not expected to be toxic by ingestion or a skin/eye irritant. More comprehensive and detailed product information is contained in the product package insert or may be found in the Physicians' Desk Reference.

12. ECOLOGICAL INFORMATION

No ecological damage or persistence in the environment expected under normal conditions of use or with proper disposal. Environmental fate and transport of this product have not been studied.

13. DISPOSAL CONSIDERATIONS**Disposal Information**

Not classified as hazardous waste. Observe all federal, state, and local regulations.

Waste Disposal Methods

Waste must be disposed in accordance with federal, state and local environmental regulations. Uncontaminated product may be disposed by flushing down the sanitary sewer, or by mixing with a liquid sorbent and then placing mixture in the solid waste container for disposal. Incineration is the preferred method of disposal for any contaminated product.

14. TRANSPORT INFORMATION**Proper Shipping Name:**

Not Regulated

Hazard Class:

Not Required

Transportation of Hazardous Material Description

Domestic DOT Label: None; International (IMO) label: Drugs/Medicines. Ship according to DOT and/or IATA regulations.

15. REGULATORY INFORMATION**TSCA**

This material is a biological product regulated by the United States Food and Drug Administration (FDA).

CERCLA

NA

SARA 302

NA

SARA 313

NA

16. OTHER INFORMATION**Prepared By:**

CSL Behring Health Safety & Environment Dept.

Approved By:

Director, Health Safety Environment & Risk Management

Approved Date:

1/22/10

Supersedes Date:

All prior versions of MSDS

Other Information

The information contained herein is based upon data considered true and accurate. CSL Behring makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Manufacturer: Bayer Corporation
Pharmaceutical Division
Biotechnology
800 Dwight Way
PO Box 1986
Berkeley, CA 94701-1986
(510) 705-5000

Revision Summary

1/22/10	Minor Editorial Changes
10/11/07	Company name change.
04/01/05	Updated manufacturer identification.
10/10/00	Original Aventis Behring MSDS prepared from manufacturer and distributor product safety information.