

## Helixate® FS

### Material Safety Data Sheet

**Effective Date:** 10/10/00

**Date Printed:** 10/12/00

**MSDS Identifier:** H03-00

**Page 1**

### 1. PRODUCT AND MANUFACTURER IDENTIFICATION

**Product Name:** Helixate® FS  
**Distributor:** Aventis Behring L.L.C.  
**Address:** 1020 First Avenue  
 PO Box 61501  
 King of Prussia, PA 19406-0901  
**Telephone Number:** (610) 878-4000  
**Emergency Telephone Number:** (800) 504-5434

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. This product is not hazardous as classified by OSHA, EPA, or DOT. An MSDS is not required by any of these regulatory authorities. Aventis Behring provides the 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)	NA	Active ingredient
<b>Others, when reconstituted to dose-form</b>		
Sucrose, USP (0.9-1.3%)	57-50-1	Stabilizer
Sodium (27-36 mEq/L)		Osmotic balance adjustment
Chloride (32-40 mEq/L)		Osmotic balance adjustment
Calcium Chloride, USP (2-3 mM)	10043-52-4	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.

## Helixate FS

### Material Safety Data Sheet

Effective Date: 10/10/00

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MSDS Identifier: H03-00

Page 2

#### 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 distributor or manufacturer at the telephone number listed in 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. Expected to be 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

#### FLAMMABLE LIMITS

Flash Pt:	NA
Flammable Limits in Air-Lower:	NA
Flammable Limits in Air-Upper:	NA
Auto-Ignition Temperature:	NA

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**Material Safety Data Sheet**

**Effective Date:** 10/10/00

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**MSDS Identifier:** H03-00

**Page 3**

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**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 to provide protection against the product. Eye protection may be required by procedure of administration.

**Skin Protection**

None required to provide protection against the product. Latex gloves may be required by procedure of administration.

**Respiratory Protection**

None required.

**Engineering Controls**

Not applicable

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**Material Safety Data Sheet**

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**MSDS Identifier:** H03-00

**Page 4**

### 9. PHYSICAL AND CHEMICAL PROPERTIES

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

**As reconstituted:**

<b>Physical Form:</b>	Clear aqueous solution
<b>Color:</b>	Colorless to faint yellow
<b>Odor:</b>	Unspecified
<b>Boiling Point:</b>	Unspecified
<b>Melting Point:</b>	Unspecified
<b>Freezing Point:</b>	Unspecified
<b>pH:</b>	6.9 ± 0.5
<b>Solubility in Water:</b>	Complete
<b>Specific Gravity:</b>	Unspecified
<b>Decomposition Temperature:</b>	Unspecified
<b>Odor Threshold:</b>	Unspecified
<b>Evaporation Rate:</b>	Unspecified
<b>Vapor Pressure:</b>	Unspecified
<b>Vapor Density:</b>	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, filtered 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 nor 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.

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**Material Safety Data Sheet**

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**MSDS Identifier:** H03-00

**Page 5**

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### 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

## Helixate® FS

**Material Safety Data Sheet**

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**MSDS Identifier:** H03-00

**Page 6**

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### 16. OTHER INFORMATION

**Prepared By:** Aventis Behring Environmental, Health, and Safety Group  
**Approved By:** Vice-President Environmental, Health, and Safety  
**Approved Date:** 10/10/00  
**Supersedes Date:** Initial version of MSDS

#### **Other Information**

The information contained herein is based upon data considered true and accurate. Aventis 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 distributor or manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

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

#### **Revision Summary**

10/10/00 Original Aventis Behring MSDS prepared from manufacturer and distributor product safety information.