

## Monoclote-P<sup>®</sup>

**Material Safety Data Sheet**
**Effective Date:** 07/20/00

**Date Printed:** 7/19/00

**MSDS Identifier:** M02-01

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### 1. PRODUCT AND MANUFACTURER IDENTIFICATION

**Product Name:** Monoclote-P<sup>®</sup>  
**Manufacturer:** 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 VIII:C (Human) <b>Others, when reconstituted to dose-form</b>	NA	Active ingredient
Albumin (Human), USP (<2%)	NA	Stabilizer
Sodium Chloride, USP (<3%)	7647-14-5	Osmotic balance adjustment
Calcium Chloride, USP (<0.5%)	10043-52-4	Osmotic balance adjustment
Mannitol, USP (<1%)	69-65-8	Stabilizer
L-Histidine, USP (<0.5%)	7006-35-1	Stabilizer
Sodium Hydroxide, ACS	1310-73-2	pH adjustment
Hydrochloric Acid, ACS	7647-01-0	pH adjustment
Water For Injection, USP	7732-18-5	Volume adjustment

### 3. HAZARDS IDENTIFICATION

#### **Potential Health Effects**

This product has been prepared from the pooled plasma of healthy adult donors. Each plasma donation has been tested for the absence of antibodies against HIV-1, HIV-2 and Hepatitis C, as well as for the absence of HIV antigen and Hepatitis B surface antigens. In addition, the product underwent 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.

#### **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 above.

#### **Eye**

No data. No adverse health effects reported nor anticipated.

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**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**

<b>Flash Pt:</b>	NA
<b>Flammable Limits in Air-Lower:</b>	NA
<b>Flammable Limits in Air-Upper:</b>	NA
<b>Auto-Ignition Temperature:</b>	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.

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### 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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### 9. PHYSICAL AND CHEMICAL PROPERTIES

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

**As reconstituted:**

**Physical Form:** Clear aqueous solution

**Color:** None

**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 Monoclote-P<sup>®</sup> is a sterile, stable white powder with biological activity indicated in the treatment of Hemophilia A. When reconstituted into its dose-form for intravenous administration, this product is a pasteurized and sterile, filtered aqueous solution containing human antihemophilic factor VIII:C, stabilizers, and osmotic and buffering agents. It also contains trace amounts of the monoclonal antibody (a mouse protein) used in the process of 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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### 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: Aventis Behring Environmental, Health, and Safety Group  
Approved By: Vice-President Environmental, Health, and Safety  
Approved Date: 07/20/00  
Supersedes Date: All prior versions of MSDS

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**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 manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

**Revision Summary**

07/20/00	Updated manufacturer identification and transportation labeling information.
05/01/97	Updated format of MSDS, updated hazard and handling information.
05/01/97	Original Aventis Behring MSDS prepared from predecessor MSDS and other product safety information.