

### Material Safety Data Sheet

Creation Date 27-May-2010

Revision Date 27-May-2010

Revision Number 1

#### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name** Pacific Hemostasis® Factor VIII Deficient Plasma, Human

**Cat No.** 100800, 200800, 250800

**Synonyms** No information available.

**Recommended Use** In vitro diagnostic

<b>Company</b> Fisher Diagnostics A Division of Fisher Scientific Company, LLC A Part of Thermo Fisher Scientific, Inc. 8365 Valley Pike Middletown, VA 22645-1905 Tel: (800) 528-0494	<b>Emergency Telephone Number</b> Chemtrec US: (800) 424-9300 Chemtrec EU: (202) 483-7616
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#### 2. HAZARDS IDENTIFICATION

##### WARNING!

##### Emergency Overview

Potential Biohazard. Contains human sourced material. Handle as potentially infectious. Handle in accordance with good industrial hygiene and safety practice. May cause eye, skin, and respiratory tract irritation .

**Appearance** Buff - Yellow

**Physical State** Lyophilized

**odor** odorless

**Target Organs** None known.

##### Potential Health Effects

##### Acute Effects

##### Principle Routes of Exposure

**Eyes**

May cause irritation.

**Skin**

May cause irritation. May be harmful in contact with skin.

**Inhalation**

May cause irritation of respiratory tract. May be harmful if inhaled.

**Ingestion**

May be harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

**Chronic Effects**

None known.

See Section 11 for additional Toxicological information.

**Aggravated Medical Conditions** No information available.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Haz/Non-haz**

Component	CAS-No	Weight %
FVIII Deficient Plasma (Human)	NA	> 98%
HEPES	7365-45-9	< 2%

### 4. FIRST AID MEASURES

<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
<b>Skin Contact</b>	Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.
<b>Inhalation</b>	Move to fresh air. If breathing is difficult, give oxygen. Get medical attention immediately if symptoms occur.
<b>Ingestion</b>	Do not induce vomiting. Obtain medical attention.
<b>Notes to Physician</b>	Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

<b>Flash Point</b>	Not applicable
<b>Method</b>	No information available.
<b>Autoignition Temperature</b>	No information available.
<b>Explosion Limits</b>	
<b>Upper</b>	No data available
<b>Lower</b>	No data available
<b>Suitable Extinguishing Media</b>	Substance is nonflammable; use agent most appropriate to extinguish surrounding fire..
<b>Unsuitable Extinguishing Media</b>	No information available.
<b>Hazardous Combustion Products</b>	No information available.
<b>Sensitivity to mechanical impact</b>	No information available.
<b>Sensitivity to static discharge</b>	No information available.

**Specific Hazards Arising from the Chemical**

Thermal decomposition can lead to release of irritating gases and vapors.

**Protective Equipment and Precautions for Firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

**NFPA**                      **Health** 1                      **Flammability** 0                      **Instability** 0                      **Physical hazards** N/A

**6. ACCIDENTAL RELEASE MEASURES**

**Personal Precautions**                      Use personal protective equipment. Ensure adequate ventilation. Avoid dust formation. Avoid contact with skin, eyes and clothing.

**Environmental Precautions**                      Should not be released into the environment.

**Methods for Containment and Clean Up**                      Avoid dust formation. Sweep up or vacuum up spillage and collect in suitable container for disposal. Dispose of cleanup material in marked biohazard container.

**7. HANDLING AND STORAGE**

**Handling**                      Handle as potentially infectious. Handle in accordance with good industrial hygiene and safety practice. Wear personal protective equipment. Ensure adequate ventilation. Avoid dust formation. Do not breathe dust. Do not get in eyes, on skin, or on clothing.

**Storage**                      Keep containers tightly closed in a dry, cool and well-ventilated place. Keep at temperatures between 2° and 8 °C.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Engineering Measures**                      Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

**Exposure Guidelines**                      This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

*NIOSH IDLH: Immediately Dangerous to Life or Health*

**Personal Protective Equipment**

**Eye/face Protection**

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166

**Skin and body protection**

Wear appropriate protective gloves and clothing to prevent skin exposure

**Respiratory Protection**

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced

**9. PHYSICAL AND CHEMICAL PROPERTIES**

<b>Physical State</b>	Lyophilized
<b>Appearance</b>	Buff - Yellow
<b>odor</b>	odorless
<b>Odor Threshold</b>	No information available.
<b>pH</b>	No information available.
<b>Vapor Pressure</b>	No information available.
<b>Vapor Density</b>	No information available.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Viscosity	No information available.
Boiling Point/Range	No information available.
Melting Point/Range	No information available.
Decomposition temperature	No information available.
Flash Point	Not applicable
Evaporation Rate	No information available.
Specific Gravity	No information available.
Solubility	Soluble in water
log Pow	No data available

## 10. STABILITY AND REACTIVITY

Stability	Stable under normal conditions.
Conditions to Avoid	Avoid dust formation. Excess heat.
Incompatible Materials	None known
Hazardous Decomposition Products	Thermal decomposition can lead to release of irritating gases and vapors
Hazardous Polymerization	Hazardous polymerization does not occur.
Hazardous Reactions .	None under normal processing.

## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity

**Product Information** No acute toxicity information is available for this product

### **Component Information**

**Irritation** No information available.

**Toxicologically Synergistic Products** No information available.

### Chronic Toxicity

**Carcinogenicity** There are no known carcinogenic chemicals in this product

**Sensitization** No information available.

**Mutagenic Effects** No information available.

**Reproductive Effects** No information available.

**Developmental Effects** No information available.

<b>Teratogenicity</b>	No information available.
<b>Other Adverse Effects</b>	The toxicological properties have not been fully investigated..
<b>Endocrine Disruptor Information</b>	No information available

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Do not empty into drains.

<b>Persistence and Degradability</b>	No information available
<b>Bioaccumulation/ Accumulation</b>	No information available
<b>Mobility</b>	No information available

## 13. DISPOSAL CONSIDERATIONS

<b>Waste Disposal Methods</b>	Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification
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## 14. TRANSPORT INFORMATION

### DOT

<b>UN-No</b>	UN2814
<b>Proper Shipping Name</b>	INFECTIOUS SUBSTANCES, AFFECTING HUMANS
<b>Hazard Class</b>	6.2

### TDG

<b>UN-No</b>	UN2814
<b>Proper Shipping Name</b>	INFECTIOUS SUBSTANCES, AFFECTING HUMANS
<b>Hazard Class</b>	6.2

### IATA

<b>UN-No</b>	UN3373
<b>Proper Shipping Name</b>	BIOLOGICAL SUBSTANCE, CATEGORY B
<b>Hazard Class</b>	6.2

### IMDG/IMO

<b>UN-No</b>	UN3373
<b>Proper Shipping Name</b>	BIOLOGICAL SUBSTANCE, CATEGORY B

14. TRANSPORT INFORMATION

Hazard Class 6.2

15. REGULATORY INFORMATION

International Inventories

Component	TSCA	DSL	NDSL	EINECS	ELINCS	NLP	PICCS	ENCS	AICS	CHINA	KECL
HEPES	X	X	-	230-907-9	-		X	-	X	X	-

Legend:

- X - Listed
- E - Indicates a substance that is the subject of a Section 5(e) Consent order under TSCA.
- F - Indicates a substance that is the subject of a Section 5(f) Rule under TSCA.
- N - Indicates a polymeric substance containing no free-radical initiator in its inventory name but is considered to cover the designated polymer made with any free-radical initiator regardless of the amount used.
- P - Indicates a commenced PMN substance
- R - Indicates a substance that is the subject of a Section 6 risk management rule under TSCA.
- S - Indicates a substance that is identified in a proposed or final Significant New Use Rule
- T - Indicates a substance that is the subject of a Section 4 test rule under TSCA.
- XU - Indicates a substance exempt from reporting under the Inventory Update Rule, i.e. Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(B)).
- Y1 - Indicates an exempt polymer that has a number-average molecular weight of 1,000 or greater.
- Y2 - Indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

U.S. Federal Regulations

TSCA 12(b) Not applicable

SARA 313  
 Not applicable

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act  
 Not applicable

Clean Air Act  
 Not applicable

OSHA  
 Not applicable

CERCLA  
 Not Applicable

**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**State Right-to-Know**

Not applicable

**U.S. Department of Transportation**

Reportable Quantity (RQ): N  
DOT Marine Pollutant N  
DOT Severe Marine Pollutant N

**U.S. Department of Homeland Security**

This product does not contain any DHS chemicals.

**Other International Regulations**

**Mexico - Grade** No information available

**Canada**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

**WHMIS Hazard Class**

D3 Biohazardous infectious materials



**16. OTHER INFORMATION**

**Prepared By** Regulatory Affairs  
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**Revision Summary** "\*\*\*\*", and red text indicates revision

**Disclaimer**

The information provided on 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

**End of MSDS**