

Material Safety Data Sheet

Creation Date 29-Apr-2010

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Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Pacific Hemostasis® Universal Coagulation Reference Plasma

Cat No. 100301, 200301, 250301

Synonyms U.C.R.P.

Recommended Use In vitro diagnostic

Company

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

Emergency Telephone Number

Chemtrec US: (800) 424-9300
Chemtrec EU: (202) 483-7616

2. HAZARDS IDENTIFICATION

CAUTION!

Emergency Overview

Potential Biohazard. Handle as potentially infectious. Handle in accordance with good industrial hygiene and safety practice. May cause eye, skin, and respiratory tract irritation. The toxicological properties have not been fully investigated.

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 %
Human Plasma	NA	> 99%
Non-hazardous Buffers and/or Stabilizers	NA	< 1%

4. FIRST AID MEASURES

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

Skin Contact Get medical attention immediately if symptoms occur. Wash off immediately with plenty of water for at least 15 minutes.

Inhalation Move to fresh air. If breathing is difficult, give oxygen. Get medical attention immediately if symptoms occur.

Ingestion Do not induce vomiting. Obtain medical attention.

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Flash Point Not applicable
Method No information available.

Autoignition Temperature No information available.

Explosion Limits
Upper No data available
Lower No data available

Suitable Extinguishing Media Substance is nonflammable; use agent most appropriate to extinguish surrounding fire..

Unsuitable Extinguishing Media No information available.

Hazardous Combustion Products No information available.

Sensitivity to mechanical impact No information available.
Sensitivity to static discharge 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. Avoid contact with skin, eyes and clothing.
Storage	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep at temperature not exceeding -25°C.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Physical State	Lyophilized
Appearance	Buff - Yellow
odor	odorless
Odor Threshold	No information available.
pH	6.5 - 7.5
Vapor Pressure	No information available.
Vapor Density	No information available.
Viscosity	No information available.
Boiling Point/Range	No information available.
Melting Point/Range	No information available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Decomposition temperature °C	No information available.
Flash Point	Not applicable
Evaporation Rate	No information available.
Specific Gravity	No information available.
Solubility	No information available.
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
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Component Information

Irritation	No information available.
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Toxicologically Synergistic Products	No information available.
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Chronic Toxicity

Carcinogenicity	There are no known carcinogenic chemicals in this product
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Sensitization	No information available.
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Mutagenic Effects	No information available.
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Reproductive Effects	No information available.
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Developmental Effects	No information available.
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Teratogenicity	No information available.
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Other Adverse Effects	The toxicological properties have not been fully investigated..
Endocrine Disruptor Information	No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Do not empty into drains.

Persistence and Degradability	No information available
Bioaccumulation/ Accumulation	No information available
Mobility	No information available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods	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

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG/IMO</u>	Not regulated

15. REGULATORY INFORMATION

International Inventories

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

15. REGULATORY INFORMATION

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 Thermo Fisher Scientific Tel: (412) 490-8929
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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