



Material Safety Data Sheet

Creation Date 03-May-2010

Revision Date 03-May-2010

Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Pacific Hemostasis® Abnormal Coagulation Reference Plasma

Cat No. 100603, 200603

Synonyms A.C.R.P.

Recommended Use In vitro diagnostic

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

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

Skin

Inhalation

Ingestion

May cause irritation.

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

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

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 | > 45% |
| Non-hazardous Buffers and/or Stabilizers | NA | < 1% |
| Sodium chloride | 7647-14-5 | < 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 Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.

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. |
| 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 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

| | |
|-----------------------|---------------------------|
| 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|------------------------------|---------------------------|
| Boiling Point/Range | No information available. |
| Melting Point/Range | No information available. |
| 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 |
|---------------------|---|

Component Information

| Component | LD50 Oral | LD50 Dermal | LC50 Inhalation |
|-----------------|----------------|--------------------|---------------------------------|
| Sodium chloride | 3 g/kg (Rat) | 10 g/kg (Rabbit) | 42 g/m ³ (Rat) 1 h |

| | |
|------------|---------------------------|
| 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. |
| Teratogenicity | No information available. |
| Other Adverse Effects | The toxicological properties have not been fully investigated.. |
| Endocrine Disruptor Information | No information available |

12. ECOLOGICAL INFORMATION

Ecotoxicity

| Component | Freshwater Algae | Freshwater Fish | Microtox | Water Flea |
|-----------------|------------------|---|------------|---------------------|
| Sodium chloride | Not listed | Pimephals prome: LC50: 7650 mg/L/96H | Not listed | EC50: 1000 mg/L/48H |

| | |
|--------------------------------------|--------------------------|
| 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 |
|-------------------------------|--|

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

| Component | TSCA | DSL | NDSL | EINECS | ELINCS | NLP | PICCS | ENCS | AICS | CHINA | KECL |
|-----------------|------|-----|------|-----------|--------|-----|-------|------|------|-------|---------------|
| Sodium chloride | X | X | - | 231-598-3 | - | | X | X | X | X | KE-31387 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
Thermo Fisher Scientific
Tel: (412) 490-8929

Creation Date

03-May-2010

Print Date

03-May-2010

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

