

Safety Data Sheet

For Frozen IVD Plasma Products

IDENTIFICATION

Supplier: Affinity Biologicals Inc.
1348 Sandhill Drive
Ancaster, ON L9G 4V5 Canada
Telephone: 905-304-9896, 1-800-903-6020 (in Canada and the United States)
Fax: 905-304-9897
Emergency Telephone: 905-304-9896 (EST 8:30 a.m. – 5:00 p.m.)
After hours contact your local poison control centre

Product Name: VisuCon™-F Frozen Normal Control Plasma, VisuCon™-F Frozen Abnormal Control Plasma, VisuCal™-F Frozen Calibrator Plasma, VisuCon™-F Frozen Unassayed Normal Control Plasma, VisuCon™-F Frozen Unassayed Abnormal Control 1 Plasma, VisuCon™-F Frozen Coag Screen N, VisuCon™-F Frozen Coag Screen ABN, VisuDep-F Frozen Factor II Deficient Plasma, VisuDep-F Frozen Factor V Deficient Plasma, VisuDep-F Frozen Factor VII Deficient Plasma, VisuDep-F Frozen Factor VIII Deficient Plasma, VisuDep-F Frozen Factor IX Deficient Plasma, VisuDep-F Frozen Factor X Deficient Plasma, VisuDep-F Frozen Factor XI Deficient Plasma, VisuDep-F Frozen Factor XII Deficient Plasma, VisuCon-F Low Fibrinogen Control Plasma

Catalogue Number: Frozen Plasmas: FRNCP0105, FRNCP0125, FRABP0105, FRABP0125, FRSP0105, FRSP0125, UFNCP0125, UFNCP0181, UFNCP0481, UFAB10125, UFAB10181, UFAB10481, FCSN0125, FCSN0181, FCSN0481, FCSAB0125, FCSAB0181, FCSAB0481, FRDP020105, FRDP020125, FRDP050105, FRDP050125, FRDP070105, FRDP070125, FRDP080105, FRDP080125, FRDP090105, FRDP090125, FRDP100105, FRDP100125, FRDP110105, FRDP110125, FRDP120105, FRDP120125, LFGCP0105, LFGCP0125 and LFGCP0181

Product use: For *in vitro* diagnostic use

HAZARDS IDENTIFICATION

POSSIBLE BIOHAZARD. Although this material was prepared with plasma collected from donors screened for CJD and which was tested at source and found negative for HBsAg, Syphilis and antibodies to HIV and HCV and non-reactive for HIV-1 rNA and HCV rNA by FDA approved tests, it should be handled by personnel trained in the proper procedures for handling potential viral contaminants. All wastes should be properly labeled and disposed of according to all international, national and local regulations.

COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name: Human Source Plasma

Hazards identification: Products derived from human plasma are potentially biohazardous material. Handle with caution as if capable of transmitting infectious agents.

CAS registry number: Not applicable

LD₅₀ (species and route): Not applicable

LC₅₀ (species and route): Not applicable

FIRST AID MEASURES

Eye and Skin Contact: In case of contact, immediately wash with soap and copious amounts of water. Consult a physician.

Inhalation: Not available

Ingestion: Drink a moderate amount of water and immediately notify medical personnel.

FIRE FIGHTING MEASURES

Conditions of flammability: Not combustible

Means of extinction - suitable: Use extinguishing media appropriate for surrounding fire conditions

Means of extinction - not suitable: Not available

Protective Equipment: When extinguishing fires use breathing apparatus with an independent source of air

Upper flammable limit: Not available

Lower flammable limit: Not available

Auto-ignition temperature: Not available

Hazardous combustion products: Not available

Explosion data-sensitivity to mechanical impact: Not available

Explosion data-sensitivity to static charge: Not available

ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear protective equipment.

Procedure to be followed in case of leak or spill: Wear protective equipment. Collect or absorb onto an inert material. Place in suitable container for prompt disposal. Label the container as to the potential hazard (viral). Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g. a 1:10 dilution of common household bleach, i.e., Clorox, which is prepared fresh each day.

HANDLING AND STORAGE

Handling procedures and equipment: Wear gloves. Avoid breathing dust or aerosols. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Keep container closed when not in use.

Storage requirements: Store at -60 °C or lower.

EXPOSURE CONTROLS / PERSONAL PROTECTION

Specific engineering controls to be used: Not specified

Personal protective equipment to be used:

Eye: Wear safety goggles (or full face-shield) depending on risk of splashes;

Skin: Wear lab coat and gloves of plastic or rubber when risk of contact

Respiratory: None specified

PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Should be in frozen state until use. Thaw to liquid prior to use.

Odour & appearance: Yellowish, translucent

Odour threshold: Not available

Specific gravity: Not available

Vapour Pressure: Not available

Vapour density: Not available

Evaporation rate: not available

Boiling point: not available

Freezing point: Not available

PH: Not available

Coefficient of water/oil distribution: Not available

STABILITY AND REACTIVITY

Conditions under which the product is chemically unstable: Product is stable

Incompatibilities: None known

Conditions of reactivity: None known

Hazardous decomposition products: None known

TOXICOLOGICAL INFORMATION

Route of entry: Include skin absorption, inhalation and ingestion

Effects of acute exposure to product: May cause irritation. Potential viral infection. Although this material was prepared with plasma collected from donors screened for CJD and which was tested at source and found negative for HBsAg, Syphilis and antibodies to HIV and HCV and non-reactive for HIV-1 rNA and HCV rNA by FDA approved tests, it should be handled by personnel trained in the proper procedures for handling potential viral contaminants.

Effects of chronic exposure to product: The chemical, physical and toxicological properties have not been thoroughly investigated

Exposure limits: Not available

Irritancy of product: see above

Sensitization to product: Not available

Carcinogenicity: Not available

Reproductive toxicity: Not available

Teratogenicity: Not available

Mutagenicity: Not available

Name of toxicologically synergistic products: Not available

ECOLOGICAL INFORMATION

No data available.

DISPOSAL CONSIDERATIONS

Waste disposal: Autoclave at 121 degrees C or higher for 40 minutes or longer. Label the container with the hazard that was present. Dispose of by means that comply with all local, state and federal regulations.

TRANSPORT INFORMATION

Special shipping information: Ship frozen on dry ice.

REGULATORY INFORMATION

This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the SDS contains all the information required by the *Controlled Products Regulations*.

OTHER INFORMATION

The above statements are provided for informational use only and are believed to be correct. Affinity Biologicals Inc. shall not in any event be liable for incidental, consequential, third party or special damages of any kind resulting from any handling, use or failure of the products or above information.

Prepared at Affinity Biologicals by the Quality Assurance department using SDS data from supplier of raw material. Address any questions to Affinity Biologicals at (800) 903-6020.

Date of preparation of the SDS: October 13, 2016