Safety Data Sheet

For Research Use Only Plasma Products

IDENTIFICATION

Supplier: **Affinity Biologicals Inc.**
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Product Name: Fibrinogen Deficient Plasma, Factor II Deficient Plasma, Factor V Deficient Plasma, Factor VII Deficient Plasma, Factor VIII Deficient Plasma, von Willebrand Factor Deficient Plasma, Factor IX Deficient Plasma, Factor X Deficient Plasma, Factor XI Deficient Plasma, Factor XII Deficient Plasma, Kininogen Deficient Plasma, Prekallikrein Deficient Plasma, Factor XIII Deficient Plasma, Protein C Deficient Plasma, Protein S Deficient Plasma, Antithrombin Deficient Plasma, Antithrombin & Heparin CoFactor II Deficient Plasma, Heparin CoFactor II Deficient Plasma, Protein C Inhibitor Deficient Plasma, α_2-Antiplasmin Deficient Plasma, C1 Inhibitor Deficient Plasma, Apolipoprotein Deficient Plasma, Plasminogen Deficient Plasma, TAFI Deficient Plasma, Plasminogen Activator Inhibitor type I Deficient Plasma, Tissue Plasminogen Activator Deficient Plasma, TPA/PAI Deficient Plasma, Low Fibrinogen Control Plasma, High Fibrinogen Control Plasma, Factor II Inhibitor Plasma, Factor V Inhibitor Plasma, Factor VII Inhibitor Plasma, Factor VIII Inhibitor Plasma, Factor IX Inibitor Plasma, Factor X Inhibitor Plasma, Factor XI Inhibitor Plasma, Factor XII Inhibitor Plasma, VisuCal™ Antigen Calibrator Plasma, VisuCon™ Normal Donor Set, Normal Plasma, Abnormal Plasma (Diluted), Abnormal Control Plasma (Mid-Level), Abnormal Control Plasma (High-Level)

Catalogue Number: Frozen Plasmas: FG-DP, FII-DP, FV-DP, FVII-DP, FVIII-DP, VWF-DP, FIX-DP. FX-DP, FXI-DP, FXII-D, KN-DP, PK-DP, FXIII-DP, PC-DP, PS-DP, ATIII-DP, ATHC-DP, HCII-DP, PCI-DP, A2AP-DP, C1INH-DP, APOH-DP, PG-DP, TAFI-DP, PAI-DP, TPA-DP, TPA/PAI-DP, LFG-CP, FG-CP, INH2-DP, INH5-DP, INH7-DP, INH8-DP, INH9-DP, INH10-DP, INH11-DP, INH12-DP, NDSET, NPP

Lyophilized Plasmas: VWF-LDP, KN-LDP, PK-LDP, FXIII-LDP, PC-LDP, PS-LDP, ATIII-LDP, ATHC-LDP, HCII-LDP, PCI-LDP, A2AP-LDP, C1INH-LDP, APOH-LDP, PG-LDP, TAFI-LDP, PAI-LDP, INH2-LDP, INH5-LDP, INH7-LDP, INH8-LDP, INH9-LDP, INH10-LDP, INH11-LDP, INH12-LDP, EIACSA-1, EIACSA-5, NP-LCP, AB-LCP, ABSM-LCP, ABSH-LCP, FG-LCP

Product use: For research use only

HAZARDS INDENTIFICATION

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

LD_{50} (species and route): Not applicable

LC_{50} (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., Chlorox, which is prepared fresh each month.

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: **Frozen:** Store at -60°C or lower. **Lyophilized**: Store at 2-8°C.

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 goat and gloves of plastic or rubber when risk of contact
Respiratory: None specified

PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Frozen: Should be in frozen state until use. Thaw to liquid prior to use.
Lyophilized: Solid. Should be reconstituted prior to use.
Odour & appearance: Frozen: Yellowish, translucent. **Lyophilized:** Pale yellow
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: Frozen: Ship frozen on dry ice.
Lyophilized: Ship at ambient or 2-8°C.

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 MSDS: February 17, 2016