KEDRION
UNITED STATES

(MATERIAL) SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT/TRADE NAME: RhoGAM® Ultra-Filtered PLUS or MICRhoGAM® Ultra-Filtered PLUS

COMMON/GENERIC NAME:	Rh_o(D) Immune Globulin (Human)
CHEMICAL FAMILY:	Aqueous solution of human plasma proteins
PRODUCT USE:	RhoGAM/MICRhoGAM is indicated for use in preventing Rh immunization.
CAS NUMBER:	None Assigned
EINECS:	None Assigned
MOLECULAR FORMULA:	No Data Available

Company Identification

KEDRION BIOPHARMA INC
Parker Plaza, 400 Kelby Street
Fort Lee, NJ 07024
USA
Telephone: 201-242-8900

Emergency Telephone Numbers

***24 Hour Emergency*:** 1-855-353-7466

***EHS*:** 1-855-353-7466

SECTION 2 – HAZARDS IDENTIFICATION

Globally Harmonized System of Classification and Labeling of Chemicals (GHS)
No hazards are expected from using this product. This product is not regulated under the United Nations Globally Harmonized System for the Classification and Labeling of Hazardous Chemicals (GHS) 2006 version; European Directive 67/648/EEC; and U.S OSHA 29 CFR 1910.1200 Hazard Communication Standard. Although a (M)SDS is not required, this document is offered as a service to customers who handle or might come in contact with this product and would like guidance.

Emergency Overview

This product poses little or no hazard if spilled and no unusual hazard is expected if involved in a fire.

EU CLASSIFICATION: The product is not regulated under European Directive 67/648/EEC.

OSHA CLASSIFICATION: The product is not regulated under U.S. OSHA 29 CFR 1910.1200 (Hazard Communication Standard).

PHYSICAL FORM: Liquid

COLOR: Colorless

ODOR: Odorless

HAZARDS: None

ROUTE OF ENTRY: Accidental, Eye contact, Skin contact, Ingestion, Appropriate route of entry – Intramuscular Injection

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None known

POTENTIAL HEALTH EFFECTS:

INHALATION:
ACUTE (IMMEDIATE): None known
CHRONIC (DELAYED): None known

SKIN:
ACUTE (IMMEDIATE): None known
CHRONIC (DELAYED): None known

EYE:
ACUTE (IMMEDIATE): None known
CHRONIC (DELAYED): None known

INGESTION:
ACUTE (IMMEDIATE): None known
CHRONIC (DELAYED): None known

MUTAGENIC EFFECTS: None known

CARCINOGENIC EFFECTS: None known

REPRODUCTIVE EFFECTS: None known

OTHER HEALTH EFFECTS: This product is prepared from pooled human plasma. Each plasma donation is tested for *HBsAg*, anti-HIV-1/2, anti-*HCV* antibodies and NAT tested for *HIV1*, *HBV, HAV*, HCV, and Parvo *B19 virus* and must be non-reactive
The product has also undergone separate manufacturing processes to remove and/or inactivate enveloped and non-enveloped viruses. However, as with all human derived products, the risk of infectivity due to known or yet unknown pathogens cannot be totally eliminated or ensured.

See Section 12 for Ecological Information

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS	%(weight)	UN;EINECS	LD50/LC50
Fractioned Human Plasma	NDA*	100%	NDA	NDA

Composition/Identification of Ingredients:

**NDA – No Data Available*

Under United Nations Globally Harmonized System for the Classification and Labeling of Hazardous Chemicals (GHS) this product is not regulated. The product mentioned above is not regulated under the European Directive 67/548/EEC. The product mentioned above is not regulated under the U.S. OSHA 29 CFR 1910.1200 Hazard Communication Standard

See Section 11 for Toxicological Information

SECTION 4 – FIRST AID MEASURES

INHALATION: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Contact a physician.

SKIN: In case of skin contact, wash affected areas with soap and water. Wash clothing and shoes before reuse. Contact a physician if contact was made with non-intact skin.

EYE: In case of contact, flush with plenty of water for at least 15 minutes. Contact a physician.

INGESTION: This product is not toxic. If swallowed, wash out mouth with water provided person is conscious. Contact a physician.

See Section 2 for Potential Health Effects

SECTION 5 – FIRE FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA: Use water, foam, CO2 or dry chemical extinguishers to contain fire.

UNSUITABLE EXTINGUISHING MEDIA: None known

FIREFIGHTING PROCEDURES: Firefighters should wear full-face, self-contained breathing apparatus and impervious protective clothing to protect against potentially toxic and irritating fumes.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None known

HAZARDOUS COMBUSTION PRODUCTS: None known

FLASH POINT: Not established
FLASH POINT TEST TYPE: N/A
EXPLOSION LIMIT: UPPER: N/A LOWER: N/A

SECTION 6 – ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear personal protection equipment as specified in Section 8.

EMERGENCY PROCEDURES: Not applicable

CONTAINMENT/CLEAN-UP MEASURES: Absorb any small spills with material suitable for aqueous solutions and dispose of in a solid waste container. For large spills, mop spilled materials with detergent/water or a 10% bleach solution and dispose in sanitary sewer.

SECTION 7 – HANDLING AND STORAGE

HANDLING: Store at 2° to 8°C. Use normal precautions for storage of a drug. Protect from freezing. Containers should be kept tightly closed to prevent contamination. Follow necessary handling and storage procedures in compliance with the Directive 2000/54/EC and the OSHA Bloodborne Pathogen Standard (29 CFR1910.1030). Avoid contact with eyes, skin or clothing. If contact occurs, wash affected area thoroughly with water and consult with a physician.

STORAGE TEMPERATURE:
Minimum: 36 °F (+2 °C)
Maximum: 46 °F (+8 °C)

SHELF LIFE: Do not use after expiration date

SPECIAL SENSITIVITY: Do not freeze.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

PPE: 

RESPIRATORY PROTECTION: Under normal conditions of use, respiratory protection is not required.

EYE/FACE PROTECTION: Face shield, safety glasses, or chemical safety goggles should be worn at minimum.

SKIN/BODY PROTECTION: Lab Coat/apron. Employees should wash their hand and face before eating, drinking or using tobacco products. Wear disposables (one-use-only) gloves, long sleeved shirts and pants.

GENERAL INDUSTRIAL HYGIENE CONSIDERATIONS: Use good industrial hygiene practices in handling this material. Availability of eye wash fountains is recommended. Employers shall provide hand washing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

ENGINEERING MEASURES/CONTROLS: Under normal conditions of use, special ventilation is not required.

LISTED EXPOSURE LIMITS: None listed

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL FORM:	Liquid	**APPEARANCE/DESCRIPTION:**	Colorless liquid
COLOR:	Colorless	**ODOR:**	None
TASTE:	NDA*	**ODOR THRESHOLD:**	NDA
BOILING POINT:	NDA	**VAPOR PRESSURE:**	NDA
MELTING POINT/FREEZING POINT:	NDA	**VAPOR DENSITY:**	NDA
SPECIFIC GRAVITY:	NDA	**EVAPORATION RATE:**	NDA
DENSITY:	NDA	**VOC (WT.):**	NDA
BULK DENSITY:	NDA	**VOC (VOL.):**	NDA
WATER SOLUBILITY:	Soluble	**VOLATILES (WT.):**	NDA
SOLVENT SOLUBILITY:	NDA	**VOLATILES (VOL.):**	NDA
VISCOSITY:	NDA	**FLASH POINT:**	NDA
HALF-LIFE:	NDA	**FLASH POINT TEST TYPE:**	NDA
OCTANOL/WATER PARTITION COEFFICIENT:	NDA	**UEL:**	NDA
COEFFICIENT OF WATER/OIL DISTRIBUTION:	NDA	**LEL:**	NDA
BIOACCUMULATION FACTOR:	NDA	**AUTOIGNITION:**	NDA
PH:	6.20 TO 7.00		

*NDA – No Data Available

SECTION 10 – STABILITY AND REACTIVITY

STABILITY: Stable under recommended storage conditions

HAZARDOUS POLYMERIZATION: Hazardous polymerization will not occur.

CONDITIONS TO AVOID: Do not freeze.

INCOMPATIBLES MATERIALS: Avoid contact with oxidizing agents, reducing agents, and water reactive materials.

HAZARDOUS DECOMPOSITION PRODUCTS: None known

SECTION 11 – TOXICOLOGICAL INFORMATION

Past experience, gathered under normal hygienic conditions, had revealed no damage to health. Medicinal products are in general non-toxic when administered in compliance with prescribed doses.

ACUTE TOXICITY: Acute toxicological data is not available.

SECTION 12 – ECOLOGICAL INFORMATION

PRODUCT INFORMATION: When handled correctly this product is not expected to cause any environmental problems. Past experience has shown no effects upon biological waste water treatment plants when used correctly.

ECOLOGICAL FATE: No information available for the product.

PERSISTENCE/DEGRADABILITY: No information available for the product.

WATER POLLUTION CLASS: No information available for the product

SECTION 13 – DISPOSAL CONSIDERATIONS

DISPOSAL: Not a known infectious waste but rather a human derived material which has undergone viral inactivation. However, the potential for a yet unrecognized contaminant could be present and all human derived materials should be handled as if the material is infectious. Dispose of waste material according to local, state, federal, and provincial environmental regulations.

SECTION 14 – TRANSPORTATION INFORMATION

INTERNATIONAL MARITIME DANGEROUS GOODS CODE (IMDG): Non-hazardous cargo. Do not freeze. Transportation temperature should be at temperatures: +2 to 8°C (+36-46° F).

SHIPPING NAME: Not Regulated for Transportation.

SECTION 15 – REGULATORY INFORMATION

No labeling necessary in accordance with EC Directives, U.S. OSHA 29 CFR 1910.1200 Hazard Communication Standard and hazardous materials regulations.

SECTION 16 – OTHER INFORMATION

PREPARATION DATE: November 2015

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This is the end of the (M)SDS