GRIFOLS

SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT/TRADE NAME: HYPER **RHO**® S/D FULL DOSE**,** HYPER **RHO**® S/D MINI-DOSE

COMMON/GENERIC NAME:	Rh_0(D) Immune Globulin (Human), USP; Immune Gamma Globulins, HyperRh_0-D
CHEMICAL FAMILY:	Aqueous solution of human plasma proteins
PRODUCT USE:	Indications and Usage: Hyper **RHO**® S/D Full Dose is used to prevent Rh Hemolytic Disease of the newborn by its administration to the Rh_0(D) negative mother; and to prevent isoimmunization in Rh_0(D) negative individuals who have been transfused with Rh_0(D) positive red blood cells. Hyper **RHO**® S/D Mini-Dose is used to prevent the isoimmmunization of the Rh_0(D) negative women at the time of spontaneous or induced abortion up to 12 weeks' gestation.
CAS NUMBER:	None Assigned
EINECS:	No Data Available
MOLECULAR FORMULA:	No Data Available

Company Identification

Grifols Therapeutics Inc.

Research Triangle Park, NC 27709
U.S.A.
Tel. 919-316-6300

Emergency Telephone Numbers

24 Hour Emergency: (919) 553-5011

EHS: (919) 553-5011

SECTION 2 - HAZARDS IDENTIFICATION

Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

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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 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 to pale yellow to pink

ODOR: Odorless

HAZARDS: None

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

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 has been tested for the absence of antibodies against HIV-1, HIV-2 and Hepatitis C and the absence of surface antigens for Hepatitis B. Additionally, mini-pools of plasma donations have been tested for the absence of the HIV-1, Hepatitis C and Hepatitis B viruses using Polymerase Chain Reaction (PCR) technology. 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

Composition/Information on Ingredients:

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

**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 or mucous membranes.

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

INGESTION: 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 in a dry place away from excessive heat. 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 European Directive 2000/54/EC and the US OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030). Avoid contact with eyes, skin or clothing. If contact occurs, wash affected area thoroughly with water and consult with a physician.

STORAGE TEMPERATURE:

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

SHELF LIFE: Do not use after expiration date.

SPECIAL SENSITIVITY: Do not freeze. Store between +2 to +8 °C (35-46°F).

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 a minimum.

SKIN/BODY PROTECTION: Lab coat/apron. Employees should wash their hands and face before eating, drinking or using tobacco products. Wear disposable gloves (one-use-only), 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

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SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL FORM:	Liquid	**APPEARANCE/DESCRIPTION:**	Colorless to pale yellow to pink liquid
COLOR:	Colorless to pale yellow to pink	**ODOR:**	Odorless
TASTE:	NDA*	**ODOR THRESHOLD:**	NDA
BOILING POINT:	NDA	**VAPOR PRESSURE:**	NDA
MELTING POINT/FREEZING POINT:	NDA	**VAPOR DENSITY:**	NDA
SPECIFIC GRAVITY:	= 1.05	**EVAPORATION RATE:**	NDA
DENSITY:	= 8.7623 lbs/gal	**VOC (WT.):**	NDA
BULK DENSITY:	NDA	**VOC (VOL.):**	NDA
WATER SOLUBILITY:	Complete (100%)	**VOLATILES (WT.):**	83 TO 95%
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:	NA**		

**NDA-NO DATA AVAILABLE; **NA – NOT APPLICABLE*

SECTION 10 - STABILITY AND REACTIVITY

STABILITY: Stable under recommended storage conditions.

HAZARDOUS POLYMERIZATION: Hazardous polymerization will not occur.

CONDITIONS TO AVOID: None known

INCOMPATIBLE 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.

CHEMICAL-PHARMACOLOGICAL EFFECT: Human immunoglobulin

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: 0 – NWG; (GERMANY) VWVWS 17.05.1999

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 accordingly. 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. Transportation temperature should be +2 to + 8°C.

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: 12/27/2012 **REVISION DATE:** 06/19/2014

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This is the end of the SDS