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Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

Trade Name: Purified Human IgG (Fc)

Material. No.: A50175H Version: 1.0 Print Date: 18 DEC 2014 Specification: A50175H Page: 1 of 5 Revision Date: 18 DEC 2014

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY UNDERTAKING

Identification of the Substance or Preparation: Purified Human Immunoglobulin G (IgG), Fc Fragment.

REACH Registration No: Not Applicable

Use of the Substance / Preparation:

Identified Use(s): For In vitro laboratory use. For professional use only.

Company Undertaking Identification:

Meridian Life Science, Inc. 5171 Wilfong Road Memphis, TN 38134 U.S.A.

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2. HAZARDS IDENTIFICATION

Classification: Void

Information Pertaining to Special Dangers for Human and Environment:

This mixture does not require labeling, based on the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest version. This mixture is not classified as hazardous according to the EC Dangerous Preparations Directive (1999/45/EC) or EC 1272/2008 (CLP).

Classification System:

The classification is in alignment with current EC (European Community) Directives. It is expanded with information from technical literature.

Physical Hazards: Not classified as a physical hazard. **Health Hazard:** Not classified as a health hazard.

Environmental Hazard: Not classified as environmental hazard.

Precautionary Statements: The chemical, physical and toxicological properties of this mixture have not been thoroughly characterized. Avoid contact with eyes and skin. Do not inhale. This mixture contains material of animal origin and should be considered as potentially capable of transmitting infectious disease.

Potential Health Effects:

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Eyes: May cause eye irritation.

Skin: May be harmful if absorbed through the skin. May cause skin irritation.

Ingestion: May be harmful if swallowed. Chronic Effects: No data available. Target Organs: No data available.



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3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Characterization (Hazardous Chemical Ingredients):

Chemical Name	EC-No.	Index-No.	CAS-No.	%	Classification	Labeling
					Symbol	R-Phrases
Sodium Azide	247-852-1	011-004-00-7	26628-22-8	0.05	None	None

Dangerous Components According to EC Criteria: None

Additional Information: For wording of the listed risk phrases, refer to Section 16.

All human source materials have tested negative for HIV 1, HIV 2, anti-HCV, anti-HBc antibodies and HBsAg. No test guarantees a product to be non-infectious. Therefore, all material derived from human fluids or tissues should be considered as potentially infectious.

4. FIRST AID MEASURES

In Case of Inhalation: If inhaled, move person into fresh air. If not breathing, give CPR. **In Case of Skin Contact:** In case of skin contact wash off with soap and plenty of water.

In Case of Eye Contact: In case of eye contact flush eyes with water.

In Case of Ingestion: If swallowed never give anything by mouth to an unconscious person. Rinse mouth with

water Consult physician.

Self-Protection of the First Aider: Follow company specific safety procedures.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Extinguishing Media Which Must Not Be Used for Safety Reasons: Unknown.

Special Exposure Hazards Arising From the Substance or Preparation Itself, Combustion Products,

Resulting Gases: Hazardous decomposition products formed under fire conditions. Nature of decomposition products not known.

Special Protective Equipment for Fire-Fighters: Fire fighters should wear NIOSH-approved or self-contained breathing apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: See Section 8.

Environmental Precautions: This product contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing system and form potentially explosive metal azides. Follow proper disposal procedures. Do not let product enter drain system.

Methods for Cleaning Up: Absorb spill with inert material/absorbent. Decontaminate the spill site following standard procedures for infectious waste. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations per Section 13.

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7. HANDLING AND STORAGE

Handling: Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage: Short-term (up to 14 days) store at 2–8°C. Long term, aliquot and store at -20°C. Avoid multiple freeze/thaw cycles. Store in original container in a dry and well-ventilated place.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limit Values:

IOELV (EU) Short-Term Value: 0.3 mg/m³ (Sodium Azide) Long-Term Value: 0.1 mg/m³ (Sodium Azide)

Exposure Controls: This product is not expected to require special ventilation controls. Facilities storing or using this product should be equipped with an eyewash fountain.

Personal Protection Equipment:

Respiratory Protection: A respirator is not expected to be required under normal conditions of use.

Hand Protection: Wear chemical resistant protective gloves.

Eye Protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH or EN 166..

Body Protection: Wear lab coat or other protective garments. Remove contaminated clothing promptly.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Liquid

Physical State: Liquid Color: Clear Odor: Not Available

Parameter	Value		
pH (20°C):	8.0		
Melting Point/Range (°C):	Not Available		
Boiling Point/Range (°C):	Not Available		
Flash Point (°C):	Not Applicable		
Ignition Temperature (°C):	Not Applicable		
Vapor Pressure (°C):	Not Available		
Density (g/cm3):	Not Available		
Bulk Density (kg/m3):	Not Available		
Water Solubility (20°C in g/L):	Fully Miscible		
Partition Coefficient	Not Available		
n-Octanol/Water (log Po/w):			
Viscosity, Dynamic (mPa s):	Not Available		
Dust Explosion Hazard:	Not Applicable		



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10. STABILITY AND REACTIVITY

Reactivity: Unknown.

Stability: Stable under ordinary conditions of storage and use.

Conditions to Avoid: No decomposition if used and stored according to specifications. **Materials to Avoid:** Halogenated hydrocarbon, Acids, Metals and Acid Chlorides.

Hazardous Decomposition Products: Hazardous decomposition products formed under fire conditions. Nature

of decomposition products not known.

11. TOXICOLOGICAL INFORMATION

Routes of exposure may include inhalation, skin absorption, and eye and skin contact.

Acute Toxicity: No data available.

Irritant and Corrosive Effects: No data available.

Sensitization: No data available.

Carcinogenicity: No data available. None of the components in this product at concentrations equal to or

greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Mutagenicity: No data available.

Reproductive Effects: No data available.

Teratogenicity: No data available.

Additional Toxicological Information: This product is not subject to classification, according to the calculation method of the General EC Classification Guidelines for preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects according to our experience and information available to us.

12. ECOLOGICAL INFORMATION

Ecotoxicity: Toxicity to daphnia and other aquatic invertebrates – EC50 – Daphnia pulex (Water flea) – 4.2 mg/L – 48 h (Sodium Azide).

Mobility in Environmental Compartments: No data available.

Adsorption/Desorption: No data available.

Persistence and Degradability: No data available.

Physical- and Photo-Chemical Elimination: No data available.

Biodegradation: No data available.

Bioaccumulative Potential: No data available.

13. DISPOSAL CONSIDERATIONS

Appropriate Disposal / Product: This product contains a small amount of sodium azide (0.05%) which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If the product enters drain, flush with a large volume of water to prevent azide build-up. Dispose of unused product, spilled substance and waste in accordance with all applicable federal, state, local and provincial environmental and waste regulations.



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14. TRANSPORT INFORMATION

Land Transport (ADR/RID/GGVSE): Not restricted. Not regulated as hazardous goods. Sea Transport (IMDG-Code/GGVSee): Not restricted. Not regulated as hazardous goods. Air Transport (ICAO-IATA/DGR): Not restricted. Not regulated as hazardous goods.

15. REGULATORY INFORMATION

EU Regulations:

	Chemical Name	EC-No.	Index-No.	CAS-No.	%	Classification	Labeling
						Symbol	R-Phrases
	Sodium Azide	247-852-1	011-004-00-7	26628-22-8	0.05	None	None

Chemical Safety Assessment: Observe general laboratory safety regulations when handling chemicals. This product is not subject to identification regulations under EC Directives.

16. OTHER INFORMATION

Exposure Scenarios:

Routes of exposure may include inhalation, skin absorption, and eye and skin contact.

Exposure Controls:

Observe general laboratory safety regulations when handling chemicals. This product is not expected to require special ventilation controls. Facilities storing or using this product should be equipped with an eyewash fountain.

Personal Protection Equipment:

Respiratory Protection: A respirator is not expected to be required under normal conditions of use.

Hand Protection: Wear chemical resistant protective gloves.

Eye Protection: Wear appropriate protective safety eye glasses or goggles.

Body Protection: Wear lab coat or other protective garments. Remove contaminated clothing promptly.

This MSDS was prepared in accordance with the hazard criteria and content requirements of the EU Dangerous Substances Directive (67/548/EEC), Dangerous Preparations Directive (1999/45/EC), the Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) (EC) No 1907/2006) and EC 1272/2008 Classification, Labeling, Packaging (CLP). These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The information contained in this Material Safety Data Sheet is believed to be accurate but does not purport to be all inclusive and should be used only as a guide for experienced personnel. It is the responsibility of the user or supplier to determine the applicability of the data to the formulation of necessary safety precautions. Meridian Life Science, Inc. shall not be held liable for any damage resulting from the use of the above product or the information contained in this Material Safety Data Sheet.

Issue Date: 18 December 2014