

Safety Data Sheet

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

Trade Name: Rheumatoid Factor Control Serum

Material. No.: GWB-T00960

Version: 1.0

Revision: 001

Specification: GWB-T00960

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Revision Date: 12 NOV 2015

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

Identification of the Substance or Preparation: Rheumatoid Factor Control Serum, Neat, sourced from Normal Human Plasma, Catalog #GWB-T00960.

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:

GenWay Biotech, Inc.
6777 Nancy Ridge Drive
San Diego, CA 92121 U.S.A.
858.458.0866

E-Mail: sales@genwaybio.com

EMERGENCY TELEPHONE: US – 1.858.458.0866

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: No data available.

Eyes: No data available. Eye exposure may cause irritation, redness and watering.

Skin: No data available.

Ingestion: No data available.

Chronic Effects: No data available.

Target Organs: No data available.



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3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Characterization (Hazardous Chemical Ingredients):

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 HIV1, HIV2, HCV 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, remove to fresh air. If breathing becomes difficult, call a physician.

In Case of Skin Contact: In case of contact, immediately wash the contact area thoroughly with soap and a large amount of water. Seek medical attention.

In Case of Eye Contact: In case of contact, immediately flush eyes with a large amount of water for at least 15 minutes while holding the eyelids open to assure that the entire surface is flushed. Seek medical attention.

In Case of Ingestion: Avoid swallowing the material. Never give anything by mouth to an unconscious or convulsing person. If conscious, rinse mouth with water. Seek medical attention.

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: Dilute aqueous solution not considered a fire hazard. May emit toxic vapors under fire conditions.

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: Follow proper disposal procedures.

Methods for Cleaning Up: Absorb the spill using absorbent materials and decontaminate the spill with a bleach solution (10%) or other germicidal agent. Wash the spill area after material pick up and decontamination is complete. 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. Handle this material as if capable of transmitting infectious agents. Observe routine biosafety precautions in handling. Wash hands thoroughly after handling.

Storage: Store at -20°C. Avoid multiple freeze/thaw cycles. Store in original container.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limit Values:

Exposure controls: This product is not expected to require special ventilation controls. Facilities storing or using this product should be equipped with an emergency shower and 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Liquid

Physical State: Liquid

Color: Pale Amber

Odor: Not Available

Parameter	Value
pH (20°C):	6.0-8.0, Neutral
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/Cm ³):	Not Available
Bulk Density (Kg/M ³):	Not Available
Water Solubility (20°C in g/L):	Fully Miscible
Partition Coefficient	Not Available
N-Octanol/Water (log Po/w):	Not Available
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. Avoid excessive heat.

Materials to Avoid: This material is not incompatible with other laboratory materials.

Hazardous Decomposition Products: None expected under normal conditions of use.

11. TOXICOLOGICAL INFORMATION

Routes of exposure may include inhalation, skin absorption, and eye and skin contact. May be harmful if swallowed or absorbed through skin.

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: No data available.

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: Decontamination of excess material using bleach solution (10%) is recommended. 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 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 Safety Data Sheet (SDS) 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 SDS 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. GenWay Biotech, Inc. shall not be held liable for any damage resulting from the use of the above product or the information contained in this SDS.