

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 as amended by Regulation (EU) No. 2020/878, and Regulation (EC) No. 1272/2008

Revision date 10-Sep-2024

Revision Number 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier			
Product Code(s)	A51300B		
Product Name	Bovine Gamma Globulin		
Other means of identification			
Pure substance/mixture	Substance		
1.2. Relevant identified uses of the substance or mixture and uses advised against			
Recommended use	In vitro diagnostic		
Uses advised against	No information available		
1.3. Details of the supplier of the safety data sheet			
<u>Manufacturer</u> Meridian Bioscience, Inc. 5171 Wilfong Road, Memphis, TN 38134 For further information, please contact:			
E-mail Address	info@meridianlifescience.com		

1.4. Emergency telephone number

Emergency Telephone Emergency telephone CHEMTREC: US: 1-800-424-9300 International: 1-703-527-3887 Philippines: 1800 1 322 0553 Taiwan: 00801-49-1821 Thailand: 1800014808 South Korea: 080-880-0454 Asia-Pacific: +65 3163 8374

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.3. Other hazards

No information available.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

SECTION 3: Composition/information on ingredients

3.1 Substances

The product contains no substances which at their given concentration, are considered to be hazardous to health

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove to fresh air.	
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.	
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.	
Ingestion	Rinse mouth.	
4.2. Most important symptoms and effects, both acute and delayed		
Symptoms	No information available.	
Effects of Exposure	No information available.	
4.3. Indication of any immediate medical attention and special treatment needed		
Note to physicians	Treat symptomatically.	

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.	
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.	
5.2. Special hazards arising from the substance or mixture		
Specific hazards arising from the chemical	No information available.	
5.3. Advice for firefighters		
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.	

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.	
For emergency responders	Use personal protection recommended in Section 8.	
6.2. Environmental precautions	See Section 12 for additional Ecological Information.	
6.3. Methods and material for containment and cleaning up		
Methods for containment	Prevent further leakage or spillage if safe to do so.	
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.	
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.	
6.4. Reference to other sections		
Reference to other sections	See section 8 for more information. See section 13 for more information.	

SECTION 7: Handling and storage

7.1. Precautions for safe handling		
Ensure adequate ventilation.		
Handle in accordance with good industrial hygiene and safety practice.		
7.2. Conditions for safe storage, including any incompatibilities		
Keep container tightly closed in a dry and well-ventilated place.		

7.3. Specific end use(s)

Identified uses Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.	
Biological occupational exposure limits	This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.	
Derived No Effect Level (DNEL) - Workers No information available		
Derived No Effect Level (DNEL) - Ge	eneral Public No information available.	
Predicted No Effect Concentration (PNEC) No information available.		
8.2. Exposure controls		
Engineering controls	No information available.	
Personal protective equipment		
Eye/face protection	No special protective equipment required.	
Skin and body protection	No special protective equipment required.	
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.	
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.	
Environmental exposure controls	No information available.	

Method

SECTION 9: Physical and chemical properties

9.1. Information on basic physical a		
Physical state	Solid	
Color	Off-white	
Odor	No information available.	
Odor threshold	No information available	
Property	Values	Remarks • Me
Melting point / freezing point	No data available	None known
Initial boiling point and boiling rang	eNo data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Flash point	No data available	Open cup
Autoignition temperature	No data available	None known
Decomposition temperature		None known
рН	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Soluble in water	Not applicable
Solubility(ies)	no data available	Not applicable
Partition coefficient	No data available	None known
Vapor pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapor density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

SECTION 10: Stability and reactivity

10.1. Reactivity		
Reactivity	No information available.	
10.2. Chemical stability		
Stability	Stable under normal conditions.	
Explosion data Sensitivity to mechanical impact Sensitivity to static discharge	t None. None.	
10.3. Possibility of hazardous reactions		
Possibility of hazardous reactions	None under normal processing.	
10.4. Conditions to avoid		
Conditions to avoid	None known based on information supplied.	
10.5. Incompatible materials		
Incompatible materials	None known based on information supplied.	
10.6. Hazardous decomposition pro	<u>ducts</u>	

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.	
Eye contact	Specific test data for the substance or mixture is not available.	
Skin contact	Specific test data for the substance or mixture is not available.	
Ingestion	Specific test data for the substance or mixture is not available.	
Symptoms related to the physical, chemical and toxicological characteristics		
Symptoms	No information available.	

Acute toxicity

Numerical measures of toxicity

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

11.2. Information on other hazards	<u>8</u>	
11.2.1. Endocrine disrupting prop	erties	
Endocrine disrupting properties	No information available.	
11.2.2. Other information		
Other adverse effects	No information available.	
SECTION 12: Ecological ir	nformation	
<u>12.1. Toxicity</u>		
Ecotoxicity		
12.2. Persistence and degradability	<u> </u>	
Persistence and degradability	No information available.	
12.3. Bioaccumulative potential		
Bioaccumulation	There is no data for this product.	
<u>12.4. Mobility in soil</u>		
Mobility in soil	No information available.	
12.5. Results of PBT and vPvB ass	essment	
PBT and vPvB assessment	The product does not contain any substance(s) classified as PBT or vPvB above the threshold of declaration.	
12.6. Endocrine disrupting proper	tios	
Endocrine disrupting properties	No information available.	
Product Information		
12.7. Other adverse effects No information available.		
SECTION 13: Disposal considerations		
13.1. Waste treatment methods		
Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.	
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Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA 14.1. UN number or ID number 14.2. UN proper shipping name 14.3. Transport hazard class(es) 14.4. Packing group 14.5. Environmental hazards 14.6. Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated No
IMDG14.1. UN number or ID number14.2. UN proper shipping name14.3. Transport hazard class(es)14.4. Packing group14.5 Environmental hazards14.6. Special precautions for user Special Provisions14.7 Maritime transport in bulk according to IMO instruments	Not regulated Not regulated Not regulated Not regulated No None No information available
RID14.1. UN number or ID number14.2. UN proper shipping name14.3. Transport hazard class(es)14.4. Packing group14.5. Environmental hazards14.6. Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated No
ADR 14.1. UN number or ID number 14.2. UN proper shipping name 14.3. Transport hazard class(es) 14.4. Packing group 14.5. Environmental hazards 14.6. Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated No

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

Contact supplier for inventory compliance status
Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIOC - New Zealand Inventory of Chemicals

15.2. Chemical safety assessment

Chemical Safety Report

No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend

SVHC: Substances of Very High Concern for Authorization: PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances

Legend Section 8: Exposure controls/personal protection

TWA	Time weighted average	STEL	Short term exposure limit
Ceiling	Maximum limit value:	*	Skin designation
+	Sensitizers		

Classification procedure			
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used		
Acute oral toxicity	Calculation method		
Acute dermal toxicity	Calculation method		
Acute inhalation toxicity - gas	Calculation method		
Acute inhalation toxicity - vapor	Calculation method		
Acute inhalation toxicity - dust/mist	Calculation method		
Skin corrosion/irritation	Calculation method		
Serious eye damage/eye irritation	Calculation method		
Respiratory sensitization	Calculation method		
Skin sensitization	Calculation method		
Mutagenicity	Calculation method		
Carcinogenicity	Calculation method		
Reproductive toxicity	Calculation method		
STOT - single exposure	Calculation method		
STOT - repeated exposure	Calculation method		
Acute aquatic toxicity	Calculation method		
Chronic aquatic toxicity	Calculation method		
Aspiration hazard	Calculation method		
Ozone	Calculation method		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC) European Chemicals Agency (ECHA) (ECHA_API) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fundicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) National Institute of Technology and Evaluation (NITE) Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization

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Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

Europe

EU SDS version information - EGHS UL release: GHS Revision 7 2023 Q1

Europe

Partial process, including GHS Wizard, NO TW