

SAFETY DATA SHEET

Issuing Date 05-Jul-2018 Revision date 23-Apr-2024 Revision Number 2

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

Product identifier

Product Name Alethia® Group B Streptococcus Test Bead

Other means of identification

Product Code(s) 2830 TB

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Uses advised against No information available

Details of the supplier of the safety data sheet

Manufacturer Address

Meridian Bioscience, Inc. 3471 River Hills Drive Cincinnati, Ohio 45244 (800) 343-3858

E-mail Address

www.meridianbioscience.com

Emergency telephone number

Emergency Telephone Emergency telephone CHEMTREC:

US: 1-800-424-9300

Philippines: 1800 1 322 0553 Taiwan: 00801-49-1821 Thailand: 1800014808 South Korea: 080-880-0454 Asia-Pacific: +65 3163 8374

International: 1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

EN Page 1/8

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

Appearance pellet Physical state No information available Odor None

Other information

Not applicable

Unknown acute toxicity 99.1098 % of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Not applicable.

<u>Mixture</u>

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

| Chemical name | CAS No. | Weight-% | Trade secret |
|-----------------------|-----------|----------|--------------|
| Albumins, blood serum | 9048-46-8 | 1.5 | * |
| Sorbitol (D-glucitol) | 50-70-4 | 0.3279 | * |

^{*}The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

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.

Ingestion Rinse mouth.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Effects of Exposure No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

EN Page 2/8

5. FIRE-FIGHTING MEASURES

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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 Pick up and transfer to properly labeled containers.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

EN Page 3/8

exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection Wear suitable gloves.

Skin and body protectionNo 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Bead
Appearance pellet
Color white
Odor None

Odor threshold No information available

Property Values Remarks • Method

No data available None known Hq No data available Melting point / freezing point None known Initial boiling point and boiling rangeNo data available None known Flash point No data available Open cup **Evaporation rate** No data available None known No data available **Flammability** None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressure No data available None known Relative vapor density No data available None known No data available Relative density None known No data available Water solubility Soluble in water Solubility in other solvents No data available None known Partition coefficient No data available None known No data available **Autoignition temperature** None known No data available Hyphen None known No data available Kinematic viscosity None known No data available Dynamic viscosity None known

Explosive properties No information available Oxidizing properties No information available

Other information

EN Page 4/8

Softening point
Molecular weight
VOC content
Liquid Density
Bulk density
No information available
No information available
No information available
No information available

10. STABILITY AND REACTIVITY

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

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.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

 ATEmix (oral)
 99,999.00
 mg/kg

 ATEmix (dermal)
 99,999.00
 mg/kg

 ATEmix (inhalation-gas)
 99,999.00
 ppm

 ATEmix (inhalation-dust/mist)
 99,999.00
 mg/l

 ATEmix (inhalation-vapor)
 99,999.00
 mg/l

Unknown acute toxicity 99.1098 % of the mixture consists of ingredient(s) of unknown toxicity

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|-----------------------|-------------------|-------------|-----------------|
| Sorbitol (D-glucitol) | 15900 mg/kg (Rat) | - | - |
| 50-70-4 | | | |

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

Skin corrosion/irritationNo information available.

EN Page 5/8

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 toxicityNo information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity The environmental impact of this product has not been fully investigated.

Persistence and degradability No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA DSL/NDSL EINECS/ELINCS ENCS IECSC KECL PICCS -

EN Page 6/8

AIIC

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

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

| Acute health hazard | No |
|-----------------------------------|----|
| Chronic Health Hazard | No |
| Fire hazard | No |
| Sudden release of pressure hazard | No |
| Reactive Hazard | No |

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

US State Regulations

This product does not contain any substances regulated by state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OF THE LAST REVISION

| NFPA_ | Health hazards 0 | Flammability 0 | Instability 0 | Special hazards - |
|-------------|------------------|----------------|--------------------|-----------------------|
| <u>HMIS</u> | Health hazards 0 | Flammability 0 | Physical hazards 0 | Personal protection - |

EN Page 7/8

Issuing Date 05-Jul-2018

Revision date 23-Apr-2024

Revision Note No information available.

Disclaimer

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Meridian Bioscience, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.

End of Safety Data Sheet

EN Page 8/8