

Issuing Date 02-Jan-2019

Revision Date 02-Jan-2019

Revision Number 1

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

Product identifier

Product name Alethia® Group A Streptococcus External Positive Control

Other means of identification

Product code 4804

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 (International) 1-703-527-3887 / For US 1-800-424-9300

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

Appearance aqueous solution **Physical state** Liquid **Odor** None

Other Information

Not applicable

Unknown acute toxicity 99.743 % of the mixture consists of ingredient(s) of unknown toxicity
99.743 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
99.743 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
99.743 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
99.743 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
99.743 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

| Chemical Name | CAS No. | Weight-% | Trade secret |
|---------------------------------|------------|----------|--------------|
| Tris hydroxymethyl aminomethane | 77-86-1 | 0.16 | * |
| Sodium azide | 26628-22-8 | 0.094 | * |

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

4. FIRST AID MEASURES

First aid measures for different exposure routes

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 Clean mouth with water and drink afterwards plenty of water.

Most important symptoms/effects, acute and delayed

Symptoms No information available.

Indication of immediate medical attention and special treatment needed, if necessary

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical No information available.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Special protective equipment 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 materials 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

| Chemical Name | ACGIH TLV | OSHA PEL | NIOSH IDLH |
|----------------------------|--|---|---|
| Sodium azide 26628-22-8 | Ceiling: 0.29 mg/m ³ Sodium azide Ceiling: 0.11 ppm Hydrazoic acid vapor | (vacated) S* (vacated) Ceiling: 0.1 ppm HN3 (vacated) Ceiling: 0.3 mg/m ³ NaN3 | Ceiling: 0.1 ppm HN3 Ceiling: 0.3 mg/m ³ NaN3 |

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.

| | |
|---------------------------------------|--|
| 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

| | |
|-----------------------|--------------------------|
| Physical state | Liquid |
| Appearance | aqueous solution |
| Color | colorless |
| Odor | None |
| Odor threshold | No information available |

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|---------------------------------------|--------------------------|-------------------------|
| pH | No data available | None known |
| Melting point / freezing point | No data available | None known |
| Boiling point/boiling range | No data available | None known |
| Flash Point | No data available | Open cup |
| Evaporation rate | No data available | None known |
| Flammability (solid, gas) | No data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability limit: | No data available | |
| Lower flammability limit: | No data available | |
| Vapor pressure | No data available | None known |
| Vapor density | No data available | None known |
| Relative density | No data available | None known |
| Water solubility | No data available | Soluble in water |
| Solubility in other solvents | No data available | None known |
| Partition coefficient | No data available | None known |
| Autoignition temperature | No data available | None known |
| Decomposition temperature | No data available | None known |
| Kinematic viscosity | No data available | None known |
| Dynamic viscosity | No data available | None known |
| Explosive properties | No information available | |
| Oxidizing properties | No information available | |

Other Information

| | |
|-------------------------|--------------------------|
| Softening point | No information available |
| Molecular weight | No information available |
| VOC Content(%) | No information available |
| Liquid Density | No information available |
| Bulk density | 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 materials | None 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

Unknown acute toxicity 99.743 % of the mixture consists of ingredient(s) of unknown toxicity
 99.743 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
 99.743 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
 99.743 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
 99.743 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
 99.743 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---|--------------------|--------------------------------------|--|
| Tris hydroxymethyl aminomethane 77-86-1 | 5900 mg/kg (Rat) | - | - |
| Sodium azide 26628-22-8 | 27 mg/kg (Rat) | 20 mg/kg (Rabbit) 50 mg/kg (Rat) | 50+mg%2fkg++(+Rat+)+20+mg%2fkg++(+Rabbit+) |

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. |

12. ECOLOGICAL INFORMATION

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

| Chemical Name | Algae/aquatic plants | Fish | Toxicity to microorganisms | Crustacea |
|----------------------------|----------------------|--|----------------------------|-----------|
| Sodium azide 26628-22-8 | - | 0.7: 96 h Lepomis macrochirus mg/L LC50 0.8: 96 h Oncorhynchus mykiss mg/L LC50 5.46: 96 h Pimephales promelas mg/L LC50 flow-through | - | - |

Persistence and degradability No information available.

Bioaccumulation No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment 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.

| Chemical Name | RCRA - Halogenated Organic Compounds | RCRA - P Series Wastes | RCRA - F Series Wastes | RCRA - K Series Wastes |
|----------------------------|--------------------------------------|------------------------|------------------------|------------------------|
| Sodium azide 26628-22-8 | - | P105 | - | - |

| Chemical Name | California Hazardous Waste Status |
|----------------------------|-----------------------------------|
| Sodium azide 26628-22-8 | Ignitable Reactive |

14. TRANSPORT INFORMATION

DOT Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA -
DSL/NDSL Complies
EINECS/ELINCS -
ENCS -

IECSC Complies
KECL -
PICCS Complies
AICS Complies

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - 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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372:.

| Chemical Name | SARA 313 - Threshold Values % |
|---------------------------|-------------------------------|
| Sodium azide - 26628-22-8 | 1.0 |

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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302):.

| Chemical Name | Hazardous Substances RQs | Extremely Hazardous Substances RQs |
|----------------------------|--------------------------|------------------------------------|
| Sodium azide 26628-22-8 | 1000 lb | 1000 lb |

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

| Chemical Name | New Jersey | Massachusetts | Pennsylvania |
|----------------------------|------------|---------------|--------------|
| Sodium azide 26628-22-8 | X | X | X |

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

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

| | | | | |
|-------------|------------------|----------------|--------------------|------------------------------------|
| <u>NFPA</u> | Health hazards 0 | Flammability 0 | Instability 0 | Physical and chemical properties - |
| <u>HMIS</u> | Health hazards 0 | Flammability 0 | Physical hazards 0 | Personal protection - |

Issuing Date 02-Jan-2019

Revision Date 02-Jan-2019

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