

Issuing Date 04-Jan-2019

Revision Date 04-Jan-2019

Revision Number 1

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

### Product identifier

**Product name** Alethia® Malaria Positive Control

### Other means of identification

**Product code** 4795, 4799

### 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](http://www.meridianbioscience.com)

### Emergency telephone number

**Emergency telephone** Emergency telephone CHEMTREC For US 1-800-424-9300 / (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

**Appearance** aqueous solution

**Physical state** Liquid

**Odor** No information available

### Other Information

Not applicable

**Unknown acute toxicity** 99.782 % of the mixture consists of ingredient(s) of unknown toxicity  
 99.782 % of the mixture consists of ingredient(s) of unknown acute oral toxicity  
 99.782 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity  
 99.782 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)  
 99.782 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)  
 99.782 % 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
Polysorbate 20	9005-64-5	16.65	*
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 <sup>3</sup> Sodium azide Ceiling: 0.11 ppm Hydrazoic acid vapor	(vacated) S* (vacated) Ceiling: 0.1 ppm HN <sub>3</sub> (vacated) Ceiling: 0.3 mg/m <sup>3</sup> NaN <sub>3</sub>	Ceiling: 0.1 ppm HN <sub>3</sub> Ceiling: 0.3 mg/m <sup>3</sup> NaN <sub>3</sub>

### 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.

<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Physical state</b>	Liquid
<b>Appearance</b>	aqueous solution
<b>Color</b>	clear
<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available

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

### Other Information

<b>Softening point</b>	No information available
<b>Molecular weight</b>	No information available
<b>VOC Content(%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

## Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	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** 99.782 % of the mixture consists of ingredient(s) of unknown toxicity  
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Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Polysorbate 20 9005-64-5	36700 µL/kg ( Rat ) 37000 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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	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	-	-
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**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	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	Complies
IECSC	Complies
KECL	Complies
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**

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	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**

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

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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**