SAFETY DATA SHEET

Issuing Date 04-Jan-2019 **Revision date** 17-Oct-2023 **Revision Number** 2

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(s) 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

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

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

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Not applicable.

Mixture

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

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

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 thoroughly with water.

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.

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 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

Chemical name	ACGIH TLV	OSHA PEL	NIOSH
Sodium azide 26628-22-8	Ceiling: 0.29 mg/m³ Sodium azide Ceiling: 0.11 ppm Hydrazoic acid vapor	(vacated) S*	Ceiling: 0.1 ppm HN3 Ceiling: 0.3 mg/m³ 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.
Hand protection	Wear suitable gloves. Impervious gloves.
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	clear
Odor	No information available
Odor threshold	No information available

Property	Values	Remarks • Method
pH	No data available	None known
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flash point	No data available	Open cup
Evaporation rate	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Relative 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
Hyphen	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

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 99.782 % of the mixture consists of ingredient(s) of unknown toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Polysorbate 20 9005-64-5	37000 mg/kg (Rat) 36700 µL/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.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues/unused products Dispose of in accordance with local regulations. This material and its container must be disposed of as hazardous waste.

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
AIIC	Complies

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 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 contains the following substances which are regulated 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

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 may contain substances regulated by 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

NFPA	**Health hazards** 0	**Flammability** 0	**Instability** 0	**Special hazards** -
HMIS	**Health hazards** 0	**Flammability** 0	**Physical hazards** 0	**Personal protection** -

Prepared By Meridian Bioscience, Inc.

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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