

Issuing Date 04-Jan-2019

Revision Date 04-Jan-2019

Revision Number 1

SAFETY DATA SHEET

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

Product identifier	
Product name	Alethia C. difficile Positive Control
Other means of identification	
Product code	4802
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 of	data sheet
<u>Manufacturer Address</u> 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

99.999 % of the mixture consists of ingredient(s) of unknown toxicity 98.999 % of the mixture consists of ingredient(s) of unknown acute oral toxicity 99.999 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity 99.999 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas) 99.999 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor) 99.999 % 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	1	*
Sodium azide	26628-22-8	0.001	*

*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.

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 Sensitivity to Static Discharge	None. 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 precautionsEnvironmental precautionsSee Section 12 for additional Ecological Information.Methods and materials for containment and cleaning upMethods for containmentPrevent further leakage or spillage if safe to do so.Methods for cleaning upPick up and transfer to properly labeled containers.Prevention of secondary hazardsClean 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	Ceiling: 0.29 mg/m ³ Sodium	(vacated) S*	Ceiling: 0.1 ppm HN3
26628-22-8	azide	(vacated) Ceiling: 0.1 ppm HN3	Ceiling: 0.3 mg/m ³ NaN3
	Ceiling: 0.11 ppm Hydrazoic	(vacated) Ceiling: 0.3 mg/m ³	
	acid vapor	NaN3	

Appropriate engineering controls

Engineering controls

Showers Eyewash stations Ventilation systems.

Individual protection measur	res, such as persona	I protective equipment
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Eye/face protection	No special protective equipment required.

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Skin and body protection No special protective equipment required.
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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 an	d chemical properties	
Physical state	Liquid	
Appearance	aqueous solution	
Color	colorless	
Odor	None	
Odor threshold	No information available	
Property	Values	Rem
pH	No data available	Non
Melting point / freezing point	No data available	Non
Boiling point/boiling range	No data available	Non
Flash Point	No data available	Ope
Evaporation rate	No data available	Non
Flammability (solid, gas)	No data available	Non
Flammability Limit in Air		Non
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	Non
Vapor density	No data available	Non
Relative density	No data available	Non
Water solubility	No data available	Solu
Solubility in other solvents	No data available	Non
Partition coefficient	No data available	Non
Autoignition temperature	No data available	Non
Decomposition temperature	No data available	Non
Kinematic viscosity	No data available	Non
Dynamic viscosity	No data available	Non
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	
	No information ovailable	

Remarks • Method

None known None known Open cup None known None known None known

None known None known Soluble in water None known None known None known None known None known

10. STABILITY AND REACTIVITY

No information available

No information available

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

Liquid Density

Bulk density

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)5,906.00 mg/kg

Unknown acute toxicity99.999 % of the mixture consists of ingredient(s) of unknown toxicity98.999 % of the mixture consists of ingredient(s) of unknown acute oral toxicity99.999 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity99.999 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)99.999 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)99.999 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)99.999 % 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.			igated.
Chemical Name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Sodium azide	-	0.7: 96 h Lepomis	-	-
26628-22-8		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	Ignitable	
26628-22-8	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/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 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	1000 lb	1000 lb
26628-22-8		

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	Х	X	Х
26628-22-8			

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	Physical and chemical	
<u>HMIS</u>	Health hazards 0	Flammability 0	Physical hazards 0	properties - Personal protection -	
Issuing Date	04-Jan-2019				
Revision Date	04-Jan-2019				
Revision Note	No information available.				

<u>Disclaimer</u>

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