

Issuing Date 10-Sep-2018

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Revision Number 1

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

### Product identifier

**Product name** Alethia C. difficile Test Bead

### Other means of identification

**Product code** 2850 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](http://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** pellet

**Physical state** Bead

**Odor** None

### Other Information

Not applicable

**Unknown acute toxicity** 99.0859 % of the mixture consists of ingredient(s) of unknown toxicity  
 99.0859 % of the mixture consists of ingredient(s) of unknown acute oral toxicity  
 99.0859 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity  
 99.0859 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)  
 99.0859 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)  
 99.0859 % 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
Albumins, blood serum	9048-46-8	1.5	*
Sorbitol (D-glucitol)	50-70-4	0.3607	*
Ethylenediaminetetraacetic acid (EDTA)	60-00-4	0.0009	*

\*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** This product, as supplied, does not contain any hazardous materials with occupational 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.

**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

<b>Physical state</b>	Bead
<b>Appearance</b>	pellet
<b>Color</b>	white
<b>Odor</b>	None
<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** 99.0859 % of the mixture consists of ingredient(s) of unknown toxicity  
 99.0859 % of the mixture consists of ingredient(s) of unknown acute oral toxicity  
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 99.0859 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sorbitol (D-glucitol) 50-70-4	15900 mg/kg ( Rat )	-	-
Ethylenediaminetetraacetic acid (EDTA) 60-00-4	2000 mg/kg ( Rat )	-	-

**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
Ethylenediaminetetraacetic acid (EDTA)	1.01: 72 h Desmodesmus subspicatus mg/L EC50	34 - 62: 96 h Lepomis macrochirus mg/L LC50	-	113: 48 h Daphnia magna mg/L EC50 Static

60-00-4		static 44.2 - 76.5: 96 h Pimephales promelas mg/L LC50 static		
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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.

### 14. TRANSPORT INFORMATION

DOT Not regulated

### 15. REGULATORY INFORMATION

#### International Inventories

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

#### **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 contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42):.

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Ethylenediaminetetraacetic acid (EDTA) 60-00-4	5000 lb	-	-	X

**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
Ethylenediaminetetraacetic acid (EDTA) 60-00-4	5000 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
Ethylenediaminetetraacetic acid (EDTA) 60-00-4	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>NFPA</b>	Health hazards 0	Flammability 0	Instability 0	Physical and chemical properties -
<b>HMIS</b>	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection -
<b>Issuing Date</b>	10-Sep-2018			
<b>Revision Date</b>	10-Sep-2018			
<b>Revision Note</b>	No information available.			
<b>Disclaimer</b>				

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**