

Issuing Date 10-Sep-2018

Revision Date 10-Sep-2018

Revision Number 1

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

Product identifier

Product name Alethia C. difficile Control Bead

Other means of identification

Product code 2850 CB

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 pellet

Physical state Bead

Odor None

Other Information

Not applicable

Unknown acute toxicity 98.7201 % of the mixture consists of ingredient(s) of unknown toxicity
 98.7201 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
 98.7201 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
 98.7201 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
 98.7201 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
 98.7201 % 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

Physical state	Bead
Appearance	pellet
Color	light yellow
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 98.7201 % of the mixture consists of ingredient(s) of unknown toxicity
 98.7201 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
 98.7201 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
 98.7201 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
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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

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
Ethylenediaminetetraacetic acid (EDTA)	1.01: 72 h Desmodosmus 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

<u>DOT</u>	Not regulated
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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

NFPA	Health hazards 0	Flammability 0	Instability 0	Physical and chemical properties -
HMIS	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection -
Issuing Date	10-Sep-2018			
Revision Date	10-Sep-2018			
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