

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 20-Jun-2022 Revision Number 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name CLOSTRIDIUM DIFFICILE TOXOID A AND B - #10505

Safety data sheet number 10505

Pure substance/mixture Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use For research use only

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

<u>Corporate Headquarters</u> <u>Manufacturer</u> <u>Legal Entity / Contact Address</u>

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1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Ireland: 353-19014670

CHEMTREC India: 000-800-100-7141 CHEMTREC South Africa: 0-800-983-611

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

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This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

	Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
İ	Sucrose 57-50-1	50 - 100	No data available	200-334-9	No data available	-	-	-
Ī	Sodium chloride 7647-14-5	10 - 20	No data available	231-598-3	No data available	-	-	-

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
	mg/kg	mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
Sucrose 57-50-1	29700	No data available	No data available	No data available	No data available
Sodium chloride 7647-14-5	3000	10000	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. 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 contactWash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

Ingestion Rinse mouth.

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4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

SECTION 5: Firefighting measures

5.1. Extinguishing media

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning upTake up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

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Handle in accordance with good industrial hygiene and safety practice. General hygiene considerations

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	European Union	Austria	Belgium	Bu	Igaria	Croatia
Sucrose 57-50-1	-	-	TWA: 10 mg/m ³	TWA: 1	0.0 mg/m ³	TWA: 10 mg/m ³ STEL: 20 mg/m ³
Chemical name	Cyprus	Czech Republic	Denmark	Es	stonia	Finland
Sucrose 57-50-1	-	-	-	TWA:	10 mg/m ³	-
Chemical name	France	Germany	Germany MAK	Gı	reece	Hungary
Sucrose 57-50-1	TWA: 10 mg/m ³	-	-		-	-
Chemical name	Ireland	Italy	Italy REL	L	atvia	Lithuania
Sucrose 57-50-1	TWA: 10 mg/m ³ STEL: 20 mg/m ³	-	TWA: 10 mg/m ³	TWA:	5 mg/m ³	TWA: 10 mg/m ³
Sodium chloride 7647-14-5	-	-	-	TWA:	5 mg/m ³	TWA: 5 mg/m ³
Chemical name	Portugal	Romania	Slovakia	Slo	ovenia	Spain
Sucrose 57-50-1	TWA: 10 mg/m ³	-	-		-	TWA: 10 mg/m ³
Chemical name	S	weden	Switzerland		Uni	ted Kingdom
Sucrose 57-50-1		-	-			/A: 10 mg/m³ EL: 20 mg/m³

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

No protective equipment is needed under normal use conditions. If exposure limits are Respiratory protection exceeded or irritation is experienced, ventilation and evacuation may be required.

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General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid

Appearance powder or cake, lyophilised

Colour Varies

Odour No information available. **Odour threshold** No information available

Values Remarks • Method Property

Melting point / freezing point No data available None known Boiling point / boiling range No data available None known Flammability (solid, gas) No data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

None known Flash point No data available **Autoignition temperature** No data available None known

None known

pH (as aqueous solution) No data available No information available

Kinematic viscosity No data available None known Dynamic viscosity No data available None known

Water solubility Soluble in water

Solubility(ies) No data available None known No data available None known Partition coefficient No data available None known Vapour pressure Relative density No data available None known

Bulk density No data available **Liquid Density** No data available

Vapour density No data available None known

Particle characteristics

Particle Size No information available **Particle Size Distribution** No information available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions
None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materialsNone known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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.

Acute toxicity

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)
ATEmix (dermal)

Oral LD50

Dermal LD50

Inhalation LC50

No information available

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
Sodium chloride	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h

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.

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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.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium chloride	-	LC50: 4747 - 7824mg/L (96h, Oncorhynchus mykiss) LC50: 5560 - 6080mg/L (96h, Lepomis macrochirus) LC50: 6020 - 7070mg/L (96h, Pimephales promelas) LC50: 6420 - 6700mg/L (96h, Pimephales promelas) LC50: =12946mg/L (96h, Lepomis macrochirus) LC50: =7050mg/L (96h, Pimephales promelas)	-	EC50: 340.7 - 469.2mg/L (48h, Daphnia magna) EC50: =1000mg/L (48h, Daphnia magna)

12.2. Persistence and degradability

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No information available. Persistence and degradability

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment		
Sodium chloride	The substance is not PBT / vPvB PBT assessment does		
	not apply		

12.6. Endocrine disrupting properties

No information available. **Endocrine disrupting properties**

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. 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.

SECTION 14: Transport information

IATA

14.1 UN number or ID number Not regulated Not regulated 14.2 UN proper shipping name 14.3 Transport hazard class(es) Not regulated 14.4 Packing group Not regulated 14.5 Environmental hazards Not applicable

14.6 Special Precautions for Users

Special Provisions None

IMDG

14.1 UN number or ID number Not regulated 14.2 UN proper shipping name Not regulated 14.3 Transport hazard class(es) Not regulated 14.4 Packing group Not regulated 14.5 Environmental hazards Not applicable

14.6 Special Precautions for Users

Special Provisions

14.7 Maritime transport in bulk

No information available according to IMO instruments

RID

14.1 UN number Not regulated

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14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special Precautions for Users

Special Provisions None

ADR

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Sodium chloride	RG 78	-
7647-14-5		

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)		
Sucrose - 57-50-1	Plant protection agent		
Sodium chloride - 7647-14-5	Plant protection agent		

EU - Biocides

International Inventories Contact supplier for inventory compliance status

15.2. Chemical safety assessment

Chemical Safety Report No information available

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SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)

European Chemicals Agency (ECHA) (ECHA_API)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision Note Significant changes throughout SDS. Review all sections

Revision date 20-Jun-2022

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

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