

SAFETY DATA SHEET



according to Commission Regulation (EU) 2020/878 as amended

Clostridium Selective Supplement

Creation date 26th February 2024
Revision date Version 3.0

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

- 1.1. Product identifier**
Substance / mixture Clostridium Selective Supplement
Number CDS80004
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
For microbiological use only.
Mixture uses advised against
The product should not be used in ways other than those referred in Section 1.
- 1.3. Details of the supplier of the safety data sheet**
Manufacturer
Name or trade name Biolab Zrt.
Address Öv utca 43., Budapest, 1141
Hungary
Phone +36-1-221-9614
E-mail SDS@biolab.hu
Web address www.biolab.hu
Competent person responsible for the safety data sheet
Name Biolab Zrt.
E-mail SDS@biolab.hu
- 1.4. Emergency telephone number**
European emergency number: 112

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
Classification of the mixture in accordance with Regulation (EC) No 1272/2008
The mixture is classified as dangerous.

Skin Sens. 1B, H317
Most serious adverse effects on human health and the environment
May cause an allergic skin reaction.

- 2.2. Label elements**
Hazard pictogram



Signal word

Warning

Hazardous substances

Sodium (6R-cis)-3-[(carbamoyloxy)methyl]-7-methoxy-8-oxo-7-(2-thienylacetamido)-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylate

Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust.
P280 Wear protective gloves.
P321 Specific treatment (see additional first aid instructions on this label).
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

SAFETY DATA SHEET

according to Commission Regulation (EU) 2020/878 as amended



Clostridium Selective Supplement

Creation date	26th February 2024	Version	3.0
Revision date			

P501 Dispose of contents/container to by handing over to the person authorized to dispose of waste or by returning to the supplier.

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended. Dust may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture.

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 33564-30-6 EC: 251-574-6	Sodium (6R-cis)-3-[(carbamoyloxy) methyl]-7-methoxy-8-oxo-7-(2-thienylacetamido)-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylate	58	Skin Sens. 1B, H317	

Full text of all classifications and hazard statements is given in the section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. Rinsing should continue at least for 10 minutes.

If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

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

If inhaled

Not expected.

If on skin

May cause an allergic skin reaction.

If in eyes

Not expected.

If swallowed

Irritation, nausea.

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

Symptomatic treatment.

SAFETY DATA SHEET

according to Commission Regulation (EU) 2020/878 as amended



Clostridium Selective Supplement

Creation date	26th February 2024	Version	3.0
Revision date			

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow runoff of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Prevent contact with skin and eyes.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Prevent contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

Storage temperature

min 2 °C, max 8 °C

7.3. Specific end use(s)

Freeze-dried mixture for the isolation of Clostridium difficile.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The mixture contains no substances for which occupational exposure limits are set.

8.2. Exposure controls

Take off contaminated clothing and wash before reuse. Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

It is not needed.

Skin protection

Hand protection: Protective gloves resistant to the product. Contaminated skin should be washed thoroughly.

SAFETY DATA SHEET

according to Commission Regulation (EU) 2020/878 as amended



Clostridium Selective Supplement

Creation date 26th February 2024
Revision date Version 3.0

Respiratory protection

It is not needed.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	solid
Colour	data not available
Odour	data not available
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

When used in the standard way, there is not any dangerous reaction with other substances.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

SECTION 11: Toxicological information

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

No toxicological data is available for the mixture.

SAFETY DATA SHEET

according to Commission Regulation (EU) 2020/878 as amended



Clostridium Selective Supplement

Creation date	26th February 2024	Version	3.0
Revision date			

Acute toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Skin corrosion/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Serious eye damage/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Respiratory or skin sensitisation

May cause an allergic skin reaction. Data for the components of the mixture are not available.

Germ cell mutagenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Carcinogenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Reproductive toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - single exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - repeated exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information

12.1. Toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

12.2. Persistence and degradability

No data are available for either the mixture or the components.

12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

12.4. Mobility in soil

No data are available for either the mixture or the components.

12.5. Results of PBT and vPvB assessment

SAFETY DATA SHEET



according to Commission Regulation (EU) 2020/878 as amended

Clostridium Selective Supplement

Creation date	26th February 2024	Version	3.0
Revision date			

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

SECTION 14: Transport information

14.1. UN number or ID number

not subject to transport regulations

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information

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

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

not available

SECTION 16: Other information

SAFETY DATA SHEET



according to Commission Regulation (EU) 2020/878 as amended

Clostridium Selective Supplement

Creation date	26th February 2024	Version	3.0
Revision date			

A list of standard risk phrases used in the safety data sheet

H317 May cause an allergic skin reaction.

Guidelines for safe handling used in the safety data sheet

P261 Avoid breathing dust.
P280 Wear protective gloves.
P321 Specific treatment (see additional first aid instructions on this label).
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/container to by handing over to the person authorized to dispose of waste or by returning to the supplier.

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR European agreement concerning the international carriage of dangerous goods by road
BCF Bioconcentration Factor
CAS Chemical Abstracts Service
CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC Identification code for each substance listed in EINECS
EINECS European Inventory of Existing Commercial Chemical Substances
EmS Emergency plan
EU European Union
EuPCS European Product Categorisation System
IATA International Air Transport Association
IBC International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO International Civil Aviation Organization
IMDG International Maritime Dangerous Goods
IMO International Maritime Organization
INCI International Nomenclature of Cosmetic Ingredients
ISO International Organization for Standardization
IUPAC International Union of Pure and Applied Chemistry
log Kow Octanol-water partition coefficient
OEL Occupational Exposure Limits
PBT Persistent, Bioaccumulative and Toxic
ppm Parts per million
REACH Registration, Evaluation, Authorisation and Restriction of Chemicals
RID Agreement on the transport of dangerous goods by rail
UN Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB Substances of unknown or variable composition, complex reaction products or biological materials
VOC Volatile organic compounds
vPvB Very Persistent and very Bioaccumulative

Skin Sens. Skin sensitization

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

SAFETY DATA SHEET

according to Commission Regulation (EU) 2020/878 as amended



Clostridium Selective Supplement

Creation date	26th February 2024	Version	3.0
Revision date			

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

Version 3.0 replaces safety sheet 2.0 on 23/05/2018

More information

Classification procedure - calculation method.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.