

## 4013062 - CLOSTRIDIUM BOTULINUM AGAR BASE

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## Information Sheet

## SECTION 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

4013062 Code:

**CLOSTRIDIUM BOTULINUM AGAR BASE** Product name

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

Intended use Laboratory chemical product. Culture medium for microbiology.

1.3. Details of the supplier of the Information Sheet

**BIOLIFE ITALIANA S.R.L.** Name

Full address Viale Monza, 272

(Milano) District and Country 20128 Milano

Italia

Tel. 0039 02 252091

e-mail address of the competent person

mktg@biolifeitaliana.it responsible for the information sheet

1.4. Emergency telephone number

For urgent inquiries refer to NHS111in England: 111

NHS24in Scotland: 111

NHS Direct in Wales: 111 or 0845 4647

In an emergency, if the patient has collapsed or is not breathing properly, call 999

## **SECTION 2. Hazards identification**

#### 2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication:

#### 2.2. Label elements

Hazard pictograms:

Signal words:

Hazard statements:

Precautionary statements:

#### 2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration ≥ 0.1%.

## **SECTION 3. Composition/information on ingredients**



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#### SECTION 3. Composition/information on ingredients ..../>>

#### 3.2. Mixtures

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EC) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

## **SECTION 4. First aid measures**

#### 4.1. Description of first aid measures

No effects requiring implementation of special first aid measures are expected. The following information represents practical indications of correct behaviour in the event of contact with a chemical product, even if not hazardous.

In case of doubt or in the presence of symptoms contact a doctor and show him this document.

In case of more severe symptoms, ask for immediate medical aid.

#### Rescuer protection

It is good practice for rescuers lending support to a person who has been exposed to a chemical substance or to a mixture to wear personal protective equipment. The nature of such protection depends on the hazard level of the substance or mixture, on the type of exposure and on the extent of the contamination. In the absence of other more specific indications, use of disposable gloves in the event of possible contact with body fluids is recommended. For the type of PPE suitable for the characteristics of the substance or mixture, see section 8.

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

Specific information on symptoms and effects caused by the product are unknown.

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

If symptoms occur, whether acute or delayed, consult a doctor.

Means to have available in the workplace for specific and immediate treatment

Running water for skin and eye wash.

## **SECTION 5. Firefighting measures**

## 5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

## 5.2. Special hazards arising from the substance or mixture

## HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

## 5.3. Advice for firefighters

#### GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

## **SECTION 6. Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

Use breathing equipment if fumes or powders are released into the air. These indications apply for both processing staff and those involved in emergency procedures.



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#### SECTION 6. Accidental release measures .../>>

#### 6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

#### 6.3. Methods and material for containment and cleaning up

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

#### 6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

## **SECTION 7. Handling and storage**

#### 7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material information sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

#### 7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

#### 7.3. Specific end use(s)

Information not available

## **SECTION 8. Exposure controls/personal protection**

#### 8.1. Control parameters

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for particulate not otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment. The above values are not TLVs, but guide values, to be used for particles that do not have their own TLV and that are insoluble or poorly soluble in water and have low toxicity.

## 8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

**EYE PROTECTION** 

None required.

RESPIRATORY PROTECTION

Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

**ENVIRONMENTAL EXPOSURE CONTROLS** 

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

## **SECTION 9. Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

**Properties** Value Information

Appearance powder Colour beige Odour not available Melting point / freezing point not available Initial boiling point not applicable Flammability not available Lower explosive limit not available



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Temperature: 25 °C

## SECTION 9. Physical and chemical properties .../>>

Upper explosive limit not available
Flash point not applicable
Auto-ignition temperature not available
Decomposition temperature not available
pH 7,2 - 7,6
Kinematic viscosity not available
Solubility not available
Partition coefficient: n-octanol/water not available

not available not available not available

Density and/or relative density not available Relative vapour density not available Particle characteristics not available

#### 9.2. Other information

Vapour pressure

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Information not available

## **SECTION 10. Stability and reactivity**

#### 10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

#### 10.2. Chemical stability

The product is stable in normal conditions of use and storage.

## 10.3. Possibility of hazardous reactions

The powders are potentially explosive when mixed with air.

#### 10.4. Conditions to avoid

Avoid environmental dust build-up.

## 10.5. Incompatible materials

Information not available

## 10.6. Hazardous decomposition products

Information not available

## **SECTION 11. Toxicological information**

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure



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#### **SECTION 11. Toxicological information** .../>>

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture: Not classified (no significant component) ATE (Oral) of the mixture: Not classified (no significant component) ATE (Dermal) of the mixture: Not classified (no significant component)

#### SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

#### 11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

## **SECTION 12. Ecological information**

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

## 12.1. Toxicity

Information not available

#### 12.2. Persistence and degradability

Information not available



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## SECTION 12. Ecological information .../>>

#### 12.3. Bioaccumulative potential

Information not available

#### 12.4. Mobility in soil

Information not available

#### 12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

#### 12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

#### 12.7. Other adverse effects

Information not available

## **SECTION 13. Disposal considerations**

#### 13.1. Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Solid residues may be suitable for disposal in an authorised landfill site.

The management of waste arising from the use or dispersal of this product must be organised in accordance with occupational safety regulations. See section 8 for possible need for PPE.

**CONTAMINATED PACKAGING** 

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

## **SECTION 14. Transport information**

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

## 14.1. UN number or ID number

not applicable

## 14.2. UN proper shipping name

not applicable

## 14.3. Transport hazard class(es)

not applicable

## 14.4. Packing group

not applicable

#### 14.5. Environmental hazards

not applicable

#### 14.6. Special precautions for user

not applicable

#### ΕN



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SECTION 14. Transport information .../>>

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

## **SECTION 15. Regulatory information**

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

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Contained substance
Point 75

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors not applicable

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0.1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls Information not available

## 15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

## **SECTION 16. Other information**

#### LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value

#### ΕN



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#### SECTION 16. Other information .../>>

- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile
- WGK: Water hazard classes (German).

#### GENERAL BIBLIOGRAPHY

- 1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
- 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
- 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
- 4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
- 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
- 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
- 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
- 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
- 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
- 13. Regulation (EU) 2017/776 (X Atp. CLP)
- 14. Regulation (EU) 2018/669 (XI Atp. CLP)
- 15. Regulation (EU) 2019/521 (XII Atp. CLP)
- 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
- 17. Regulation (EU) 2019/1148
- 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
- 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
- 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
- 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
- 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- 23. Delegated Regulation (UE) 2023/707
- 24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)
- 25. Delegated Regulation (UE) 2023/1435 (XX Atp. CLP)
- 26. Delegated Regulation (UE) 2024/197 (XXI Atp. CLP)
- The Merck Index. 10th Edition
- Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals Ministry of Health and ISS (Istituto Superiore di Sanità) Italy

#### Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

#### CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.