

## Amylase

## Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878 and to Annex II to UK REACH

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

## 1.1. Product identifier

Code: 04-140808  
Product name: Amylase

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

Intended use: In vitro medical-diagnostic disposable. Reagent for microscopy.

## 1.3. Details of the supplier of the safety data sheet

Name: BIO-OPTICA MILANO SPA  
Full address: via San Faustino, 58  
District and Country: 20134 Milano (MI)  
Italia  
Tel.: 0039 02 2127131  
Fax: 0039 02 2153000

e-mail address of the competent person responsible for the Safety Data Sheet

info@bio-stain.it

Supplier: Bio-Optica Milano S.p.a.

## 1.4. Emergency telephone number

For urgent inquiries refer to: 0845 46 47, Poison centres NHS Direct in England or Wales  
08454 24 24 24, Poison centres NHS 24 in Scotland

## 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). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to (EU) Regulation 2020/878.

Hazard classification and indication: --

## 2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements:

**EUH210** Safety data sheet available on request.  
**EUH208** Contains: Amylase  
May produce an allergic reaction.

Precautionary statements: --

## 2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage  $\geq$  than 0,1%.The product does not contain substances with endocrine disrupting properties in concentration  $\geq$  0.1%.

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## SECTION 3. Composition/information on ingredients

### 3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
<b>Amylase</b>		
CAS	9000-90-2	0 ≤ x < 0,5
EC	232-565-6	Resp. Sens. 1 H334
INDEX	647-015-00-4	

The full wording of hazard (H) phrases is given in section 16 of the sheet.

## SECTION 4. First aid measures

### 4.1. Description of first aid measures

Not specifically necessary. Observance of good industrial hygiene is recommended.

### 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

Information not available

## 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.

### 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.

### 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

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

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 safety data 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

Information not available

### 8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

#### HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

#### SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

#### EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

#### RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

#### 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	liquid	
Colour	colourless	
Odour	odourless	
Melting point / freezing point	Not available	

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

Initial boiling point	Not available
Flammability	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Flash point	> 60 °C
Auto-ignition temperature	Not available
pH	Not available
Kinematic viscosity	Not available
Solubility	soluble in water
Partition coefficient: n-octanol/water	Not available
Vapour pressure	Not available
Density and/or relative density	Not available
Relative vapour density	Not available
Particle characteristics	Not applicable

### 9.2. Other information

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

No hazardous reactions are foreseeable in normal conditions of use and storage.

### 10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

### 10.5. Incompatible materials

Information not available

### 10.6. Hazardous decomposition products

Information not available

## SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

### 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

May produce an allergic reaction.

Contains:

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### Respiratory sensitization

Information not available

### Skin sensitization

Information not available

### 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

### Adverse effects on sexual function and fertility

Information not available

### Adverse effects on development of the offspring

Information not available

### Effects on or via lactation

Information not available

### STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

### Target organs

Information not available

### Route of exposure

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

Information not available

### STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

### Target organs

Information not available

### Route of exposure

Information not available

### 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

### 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  $\geq$  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.

#### CONTAMINATED PACKAGING

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

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## 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

### 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  
None

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  $\geq$  than 0,1%.

Substances subject to authorisation (Annex XIV REACH)  
None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:  
None

Substances subject to the Rotterdam Convention:  
None

Substances subject to the Stockholm Convention:  
None

Healthcare controls \_\_\_\_\_

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## SECTION 15. Regulatory information ... / &gt;&gt;

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

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

<b>Resp. Sens. 1</b>	Respiratory sensitization, category 1
<b>H334</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>EUH210</b>	Safety data sheet available on request.

## 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 as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- 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
- 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 as for REACH Regulation
- 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)



**Amylase****SECTION 16. Other information** ... / >>

- 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 Section 11.

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

**Changes to previous review:**

The following sections were modified:

02 / 09 / 11 / 12 / 15 / 16.