

According to 1907/2006/EC (REACH), 453/2010/EC

Trypsin - EDTA 1X Lyophilised w/ Sodium Chloride PM-T1717



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier: Trypsin - EDTA 1X Lyophilised w/ Sodium Chloride

PM-T1717

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

Relevant uses: Used in biotechnology. For professional use only.

Uses advised against: All uses not specified in this section or in section 7.3

1.3 Details of the supplier of the safety data sheet: BIOSERA FRANCE SAS

Headquarters: ZI du Bousquet 31360 BOUSSENS France Administrative address: Rue du Vieux Bourg 49340 NUAILLE

- France

Phone: 00 33 561 97 69 69 – E-mail: info@biosera.com www.biosera.com

..4 Emergency telephone number: ORFILA: 01 45 42 59 59

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Directive 67/548/EC and Directive 1999/45/EC:

This product was classified in accordance with Directive 67/548/EC and Directive 1999/45/EC, adapting the requirements to Regulation (EC) n°1907/2006 (REACH regulation).

Xn: R42 - May cause sensitisation by inhalation

CLP Regulation (EC) nº 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) no 1272/2008.

Resp. Sens. 1: Sensitisation, respiratory, Category 1

2.2 Label elements:

Directive 67/548/EC and Directive 1999/45/EC:

In accordance with the legislation, the elements on the label are as follows:



R Phrases:

R42: May cause sensitisation by inhalation

S Phrases:

S22: Do not breathe dust

S23: Do not breathe vapour and spray

S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

Supplementary information:

Non-applicable

Substances that contribute to the classification:

Trypsin

CLP Regulation (EC) nº 1272/2008:

Dange



Hazard statements:

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements:

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SECTION 2: HAZARDS IDENTIFICATION (continue)

P261: Avoid breathing dust/fume/gas/mist/vapours/spray

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing

P501: Dispose of the contents/containers in accordance with the current legislation on waste treatment

Supplementary information:

Non-applicable

Substances that contribute to the classification

Trypsin

2.3 Other hazards:

Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical description: Mixture composed of organic substances

Components:

In accordance with Annex II of Regulation (EC) nº1907/2006 (point 3), the product contains:

| Identification | Chemical name/Classification | | | |
|---------------------------------|------------------------------|--|-------|-------------|
| CAS: 9002-07-7 EC: 323,650.8 | Trypsin | ATP | CLP00 | |
| Index: 232-030-0 | | Xi: R36/37/38; Xn: R42 | × | 2,5 - <10 % |
| REACH: Non-applicable | Regulation 1272/2008 | Eye Irrit. 2: H319; Resp. Sens. 1: H334; Skin Irrit. 2: H315; STOT SE 3: H335 - Danger | ()(♦) | |

To obtain more information on the risk of the substances consult sections 8, 11, 12 and 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the MSDS of this product.

By inhalation:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply,etc.) requiring immediate medical assistance.

By skin contact:

This product is not classified as dangerous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or shower the person affected if necessary thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the MSDS of the product.

By consumption:

Do not induce vomiting, but if it does happen keep the head up to avoid inhalation. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

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SECTION 5: FIREFIGHTING MEASURES (continue)

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive subproducts are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/FC

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflamation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal See sections 8 and 13.

6.2 Environmental precautions:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and destroy using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, manipulation and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container.

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

Nuisance dust: Inhalable dust 10 mg/m3 // Respirable dust 4 mg/m3

DNEL (Workers):

Non-applicable

DNEL (Population):

Non-applicable

PNEC:

Non-applicable

8.2 Exposure controls:

A.- General security and hygiene measures in the work place

As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding ""CE marking"" in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more infomation see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|--|-----------------------------------|-----------|---------------------|--|
| Mandatory respiratory tract protection | Filter mask for gases and vapours | CAT III | EN 405:2001+A1:2009 | Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment. |

C.- Specific protection for the hands

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|---------------------------|----------------------------|-----------|---|--|
| Mandatory hand protection | Chemical protective gloves | CATI | EN 374-1:2003 EN 374-3:2003/AC:2006 EN 420:2003+A1:2009 | Replace the gloves at any sign of deterioration. |

D.- Ocular and facial protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|---------------------------|--|-----------|---|---|
| Mandatory face protection | Panoramic glasses against liquid splash | CATII | EN 166:2001 EN 172:1994/A1:2000 EN 172:1994/A2:2001 EN ISO 4007:2012 | Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. |

E.- Bodily protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|-----------|----------------------|-----------|--|----------------------------|
| | Work clothing | CATI | EN ISO 13688:2013 | For professional use only. |
| | Anti-slip work shoes | CATII | EN ISO 20347:2012 EN ISO 20344:2011 | None |

F.- Additional emergency measures

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

| Emergency measure | Standards | Emergency measure | Standards |
|-------------------|--------------------------------|-------------------|-------------------------------|
| Emergency shower | ANSI Z358-1 ISO 3864-1:2002 | Eyewash stations | DIN 12 899 ISO 3864-1:2002 |

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatil organic compounds:

With regard to Directive 1999/13/EC, this product has the following characteristics:

V.O.C. (Supply): 0 % weight
V.O.C. density at 20 °C: 0 kg/m³ (0 g/L)
Average carbon number: Non-applicable
Average molecular weight: Non-applicable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Solid

Appearance: Not available
Color: Not available
Odor: Not available

Volatility:

Boiling point at atmospheric pressure:

Vapour pressure at 20 °C:

Vapour pressure at 50 °C:

Non-applicable *

Non-applicable *

Non-applicable *

Non-applicable *

Product description:

Density at 20 °C:

Relative density at 20 °C:

Non-applicable *

Vapour density at 20 °C:

Partition coefficient n-octanol/water 20 °C:

Solubility in water at 20 °C:

Non-applicable *

Melting point/freezing point:

Non-applicable *

Flammability:

Flash Point: Non Flammable (>60 °C)
Autoignition temperature: Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continue)

Lower flammability limit: Non-applicable *
Upper flammability limit: Non-applicable *

9.2 Other information:

Surface tension at 20 °C: Non-applicable *
Refraction index: Non-applicable *

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected if the following technical instructions storage of chemicals. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

| Shock and friction | Contact with air | Increase in temperature | Sunlight | Humidity |
|--------------------|------------------|-------------------------|----------------|----------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

10.5 Incompatible materials:

| Acids | Water | Combustive materials | Combustible materials | Others |
|----------------|----------------|----------------------|-----------------------|----------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO2), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for consumption. For more information see section 3.

B- Inhalation:

Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for inhalation. For more information see section 3.

C- Contact with the skin and the eyes:

Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for skin contact. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.

E- Sensitizing effects:

Prolonged exposure can result in specific respiratory hypersensitivity.

F- Specific target organ toxicity (STOT)-time exposure:

^{*}Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 11: TOXICOLOGICAL INFORMATION (continue)

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Not available

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the ecotoxicological properties of the product itself is not available

12.1 Toxicity:

Not available

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

| Code | Description | Waste class (Directive 2008/98/EC) |
|-----------|--|------------------------------------|
| 16 03 05* | Organic wastes containing dangerous substances | Dangerous |

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2000/532/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) $n^{o}1907/2006$ (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2000/532/EC: Commission Decision of 3 May 2000

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2013 and RID 2013:

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SECTION 14: TRANSPORT INFORMATION (continue)

14.1UN number:Non-applicable14.2UN proper shipping name:Non-applicable14.3Transport hazard class(es):Non-applicableLabels:Non-applicable14.4Packing group:Non-applicable

14.5 Dangerous for the No

environment:

14.6 Special precautions for user

Special regulations: Non-applicable
Tunnel restriction code: Non-applicable
Physico-Chemical properties: see section 9
Limited quantities: Non-applicable

14.7 Transport in bulk according to Non-applicable

Annex II of MARPOL 73/78

and the IBC Code:
Transport of dangerous goods by sea:

With regard to IMDG 36-12:

14.1 UN number: Non-applicable
 14.2 UN proper shipping name: Non-applicable
 14.3 Transport hazard class(es): Non-applicable
 Labels: Non-applicable
 14.4 Packing group: Non-applicable

14.5 Dangerous for the

environment:

14.6 Special precautions for user

Special regulations: Non-applicable

No

EmS Codes:

Physico-Chemical properties: see section 9
Limited quantities: Non-applicable

14.7 Transport in bulk according to Non-applicable

Annex II of MARPOL 73/78 and the IBC Code:

Transport of dangerous goods by air:

With regard to IATA/ICAO 2014:

14.1 UN number: Non-applicable
 14.2 UN proper shipping name: Non-applicable
 14.3 Transport hazard class(es): Non-applicable
 Labels: Non-applicable
 14.4 Packing group: Non-applicable

14.5 Dangerous for the No environment:

14.6 Special precautions for user

Physico-Chemical properties: see section 9

14.7 Transport in bulk according to Non-applicable Annex II of MARPOL 73/78

and the IBC Code:

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Active substances for which a decision of non-inclusion onto Annex I (Regulation (EU) No 528/2012): Non-applicable

Regulation (EC) 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

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SECTION 15: REGULATORY INFORMATION (continue)

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII, REACH):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

Non-applicable

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N^0 1907/2006 (Regulation (EC) N^0 453/2010)

Modifications related to the previous security card which concerns the ways of managing risks. :

Non-applicable

Text of R-phrases considered in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

Directive 67/548/EC and Directive 1999/45/EC:

R36/37/38: Irritating to eyes, respiratory system and skin

R42: May cause sensitisation by inhalation

CLP Regulation (EC) no 1272/2008:

Eye Irrit. 2: H319 - Causes serious eye irritation

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Skin Irrit. 2: H315 - Causes skin irritation

STOT SE 3: H335 - May cause respiratory irritation

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

http://esis.jrc.ec.europa.eu

http://echa.europa.eu

http://eur-lex.europa.eu

Abbreviations and acronyms:

- ADR: European agreement concerning the international carriage of dangerous goods by road
- -IMDG: International maritime dangerous goods code
- -IATA: International Air Transport Association
- -ICAO: International Civil Aviation Organisation
- -COD: Chemical Oxygen Demand
- -BOD5: 5-day biochemical oxygen demand
- -BCF: Bioconcentration factor
- -LD50: Lethal Dose 50
- -CL50: Lethal Concentration 50
- -EC50: Effective concentration 50
- -Log-POW: Octanol-water partition coefficient
- -Koc: Partition coefficient of organic carbon

The information contained in this security data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this security data sheet only refers to this product, which should not be used for needs other than those specified.

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