



Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Revision date: 08/11/2024 Supersedes version of: 03/04/2023 Version: 2.0

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

1.1. Product identifier	
Product form Substance name Chemical name EC Index-No. EC-No. CAS-No. Product code	<ul> <li>Substance</li> <li>Trypsin</li> <li>647-010-00-7</li> <li>232-650-8</li> <li>9002-07-7</li> <li>201700383</li> </ul>
1.2. Relevant identified uses of the substa	nce or mixture and uses advised against
Relevant identified uses Use of the substance/mixture Function or use category	<ul> <li>Scientific research and development Technical testing and analysis</li> <li>For professional use only</li> <li>Laboratory chemicals</li> </ul>
0.7	
Uses advised against Restrictions on use	: Not for food, drug or home use
1.3. Details of the supplier of the safety da	ta sheet
European Directorate for the Quality of Medicines & EDQM, Council of Europe 7, Allée Kastner, CS30026 F 67081 Strasbourg France T +33(0)388412035, F +33(0)388412771 sds@edqm.eu, www.edqm.eu	4 Healthcare
1.4. Emergency telephone number	
Emergency number	: +33(0)390215608

## **SECTION 2: Hazards identification**

B [CLP]			
H334			
H319			
H315			
H335			
	H334 H319 H315	H334 H319 H315	H334 H319 H315

### Adverse physicochemical, human health and environmental effects

Causes serious eye irritation. Causes skin irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation.

## 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Signal word (CLP)	: Danger
Hazard statements (CLP)	: H315 - Causes skin irritation.
	H319 - Causes serious eye irritation.
	H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
	H335 - May cause respiratory irritation.
Precautionary statements (CLP)	: P261 - Avoid breathing dust.
	P280 - Wear protective gloves.
	P284 - respiratory protection.
	P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or
	doctor/physician.
Labelling according to: Exemption for inner	packaging where the contents do not exceed 10ml.
Hazard pictograms (CLP)	
	GHS08
2.3. Other hazards	

Other information

: Active substance (in pharmaceutical products). Warning - substance not yet tested completely.

# SECTION 3: Composition/information on ingredients

## 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Trypsin	CAS-No.: 9002-07-7 EC-No.: 232-650-8 EC Index-No.: 647-010-00-7	≤ 100	Resp. Sens. 1, H334 Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT SE 3, H335

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

SECTION 4: First aid measures	
4.1. Description of first aid measures	
First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	<ul> <li>Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If experiencing respiratory symptoms: Call a poison center or a doctor.</li> </ul>
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Get medical advice if skin irritation persists.
First-aid measures after eye contact	<ul> <li>Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.</li> </ul>
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.
4.2. Most important symptoms and e	ffects, both acute and delayed
Symptoms/effects after inhalation	<ul> <li>May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation.</li> </ul>
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.
4.3. Indication of any immediate med	ical attention and special treatment needed
No additional information available	

No additional information available

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media	<ul> <li>Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.</li> <li>Do not use a heavy water stream.</li> </ul>
5.2. Special hazards arising from the subst	,
Hazardous decomposition products in case of fire	<ul> <li>Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.</li> </ul>
5.3. Advice for firefighters	
Firefighting instructions Protection during firefighting	<ul> <li>Prevent fire fighting water from entering the environment.</li> <li>Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.</li> </ul>

SECTION 6: Accidental release	measures
6.1. Personal precautions, protect	ive equipment and emergency procedures
General measures	: Avoid contact with skin, eyes and clothing.
For non-emergency personnel	
Emergency procedures	: Evacuate unnecessary personnel.
For emergency responders	
Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containme	ent and cleaning up
For containment Methods for cleaning up	<ul> <li>Absorb with an inert material and place in an appropriate waste disposal container.</li> <li>Clean contaminated surfaces with an excess of water. Clean with the help of detergents.</li> </ul>
6.4. Reference to other sections	

See Section 13 for disposal information.

SECTION 7: Handling and stor	age
7.1. Precautions for safe handling	
Precautions for safe handling Hygiene measures	<ul> <li>Avoid all unnecessary exposure. Ensure good ventilation of the work station.</li> <li>Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.</li> </ul>
7.2. Conditions for safe storage, in	ncluding any incompatibilities
Storage conditions	Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials	: Keep in original containers.
7.3. Specific end use(s)	
No additional information available	

No additional information available

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

### No additional information available

### 8.2. Exposure controls

### Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### **Personal protection equipment**

### Eye and face protection

#### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

#### Skin protection

#### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

#### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

### **Respiratory protection**

### Respiratory protection:

In case of dust formation use respirator with filter: P3

**SECTION 9: Physical and chemical properties** 

9.1. Information on basic physical and ch	nemical properties
Physical state	: Solid
Colour	: Not available
Appearance	: Powder.
Odour	: Not available
Odour threshold	: Not available
Melting point	: 256 – 258 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
рН	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

No additional information available

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 10: Stability and reactivity	
10.1. Reactivity	
No additional information available	
10.2. Chemical stability	
No additional information available	
10.3. Possibility of hazardous reactions	
No additional information available	
10.4. Conditions to avoid	
No additional information available	
10.5. Incompatible materials	
No additional information available	
10.6. Hazardous decomposition products	
No additional information available	

# SECTION 11: Toxicological information

cute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)
Trypsin (9002-07-7)	
LD50 oral rat	> 2000 mg/kg (RTECS No YN5075000)
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Technical impossibility to obtain the data)

## 11.2. Information on other hazards

No additional information available

# SECTION 12: Ecological information

12.1. Toxicity	
Hazardous to the aquatic environment, short–term (acute) Hazardous to the aquatic environment, long–term (chronic)	<ul> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> </ul>
12.2. Persistence and degradability	
Trypsin (9002-07-7)	
Persistence and degradability	Rapidly degradable

08/11/2024 (Revision date)

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

12.3. Bioaccumulative potential
No additional information available
12.4. Mobility in soil
No additional information available
12.5. Results of PBT and vPvB assessment
No additional information available
12.6. Endocrine disrupting properties
No additional information available
12.7. Other adverse effects
No additional information available

## **SECTION 13: Disposal considerations**

13.1. Waste treatment methods

No additional information available

# **SECTION 14: Transport information**

#### In accordance with ADR / IMDG / IATA

ADR	IMDG	ΙΑΤΑ		
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable		
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable		
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable		
14.4. Packing group				
Not applicable	Not applicable	Not applicable		
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable		
No supplementary information available				

14.6. Special precautions for user

Overland transport Not applicable

Transport by sea Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

## **SECTION 15: Regulatory information**

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

### **EU-Regulations**

**REACH Annex XVII (Restriction List)** 

Not listed on REACH Annex XVII

### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

### **REACH Candidate List (SVHC)**

Not listed on the REACH Candidate List

#### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

## Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

## **SECTION 16: Other information**

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	Added
	Revision date	Added
	Issue date	Modified
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects after ingestion	Removed
4.2	Symptoms/effects after skin contact	Modified
4.2	Symptoms/effects after inhalation	Modified

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes			
Section	Changed item	Comments	
4.2	Symptoms/effects after eye contact	Modified	
4.2	Symptoms/effects	Removed	
4.3	Other medical advice or treatment	Removed	
5.1	Unsuitable extinguishing media	Added	
5.1	Suitable extinguishing media	Modified	
5.2	Hazardous decomposition products in case of fire	Added	
5.2	Fire hazard	Removed	
5.3	Protection during firefighting	Added	
5.3	Firefighting instructions	Modified	
6.1	Protective equipment	Added	
6.1	Emergency procedures	Modified	
6.1	General measures	Modified	
6.2	Environmental precautions	Added	
6.3	For containment	Added	
6.3	Methods for cleaning up	Modified	
6.4	Reference to other sections (8, 13)	Added	
7.1	Additional hazards when processed	Removed	
7.1	Precautions for safe handling	Modified	
7.1	Hygiene measures	Modified	
7.2	Packaging materials	Added	
7.2	Technical measures	Removed	
7.2	Storage conditions	Modified	
7.3	Specific end uses	Removed	
8.2	Eye protection	Modified	
8.2	Appropriate engineering controls	Modified	
8.2	Respiratory protection	Modified	
8.2	Hand protection	Modified	
8.2	Skin and body protection	Modified	
9	Odour	Removed	
10.1	Reactivity	Removed	
10.5	Incompatible materials	Removed	
10.6	Hazardous decomposition products	Removed	
11.1	LD50 oral rat	Added	
12.1	Ecology - general	Removed	
13.1	Regional waste regulation	Removed	

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Full text of H- and EUH-statements:		
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H315	Causes skin irritation.	
H319	Causes serious eye irritation.	
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
H335	May cause respiratory irritation.	
Resp. Sens. 1	Respiratory sensitisation, Category 1	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.