Safety Data Sheet (SDS)

Prepared in accordance with Regulation (EC) No. 1907/2006 as amended by Regulation (EC) No. 2020/878 and Regulation (EU) No. 1272/2008

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

1.1. Product identifier

178 003
Otoferlin, affinity purified
50 µg

Pure substance/mixture:	Mixture

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

Recommended use:	Lyophilized preparation containing proteins or peptides for research use only. Intended for reconstitution with water according to the product instructions.
Uses advised against:	Not for therapeutic or diagnostic use in humans or animals

Additional information	The product is supplied in lyophilized form. After reconstitution according to the instructions for use, the working solution contains <0.1% w/v sodium azide.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Synaptic Systems GmbH
Rudolf-Wissell Str. 28a
37079 Goettingen
Germany

Tel:	+49 (0) 551 50556-0
E-Mail:	sales@sysy.com

1.4. Emergency telephone number

Tel CHEMTREC ®:	1-800-424-9300

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]:

Not classified as hazardous substance/mixture based on available composition information.

The mixture contains **sodium azide (0.58% w/w)**. Sodium azide has a harmonised classification in CLP as **Acute Tox. 2 (H300), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), with supplemental hazard statement EUH032**

The product is supplied as a lyophilized preparation. The sodium azide concentration stated in this Safety Data Sheet refers to the product **as supplied**. After reconstitution according to the instructions for use, the resulting working solution contains **< 0.1% w/v sodium azide**.

2.2. Label elements

No label elements required for the mixture as supplied, based on current classification assessment.

Supplemental hazard information:
EUH032: Contact with acids liberates very toxic gas.

Additional labelling information:
Contains sodium azide.

The product is supplied as a lyophilized preparation. The sodium azide concentration stated in this Safety Data Sheet refers to the product **as supplied**. After reconstitution according to the instructions for use, the resulting working solution contains **< 0.1% w/v sodium azide**.

2.3 Other hazards

Product is supplied as a **lyophilised powder.** Contains sodium azide as a preservative. Avoid dust generation. Avoid contact with skin, eyes, and clothing. Contact with acids may release toxic hydrazoic acid gas. Sodium azide may form shock-sensitive metal azides in contact with lead or copper. Avoid release into drains or plumbing systems containing these metals.

SECTION 3: Composition/information on ingredients

3.1 Mixtures

Chemical name	CAS-No	EC-No	Classification according to EG No. 1272/2008 (CLP)	Concentration % (w/w)
Potassium dihydrogen phosphate (KH_2PO_4)	7778-77-0	231-931-4	not classified	0.6% (w/w)
di-Sodium hydrogen phosphate (Na_2HPO_4)	7558-79-4	231-448-7	not classified	3.3% (w/w)
Sodium chloride (NaCl)	7647-14-5	231-598-3	not classified	33.9% (w/w)
Potassium chloride (KCl)	7447-40-7	231-211-8	not classified	0.5% (w/w)
Sodium azide	26628-22-8	247-852-1	Acute Tox. 2 (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) (EUH032)	0.6% (w/w)

For the text of the H- and EUH-phrases, see Section 16

Notes:

- The product is a **lyophilisate**.
- The mixture is intended to be **reconstituted with water by the customer**.
- **After reconstitution, sodium azide concentration is < 0.1%**.

Estimation of Acute Toxicity

If no LD50/LC50 data are available or do not correspond to the classification category, the corresponding conversion factor from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD 50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 (4 h) Dust/mist - mg/L	Inhalation LC50 (4 h) Vapor - mg/L	Inhalation LC50 (4 h) Gas - ppm
Potassium dihydrogen phosphate (KH_2PO_4)	4.640	>2.000	no data available	no data available	no data available
di-Sodium hydrogen phosphate (Na_2HPO_4)	>2.000	>2.000	no data available	no data available	no data available
Sodium chloride (NaCl)	3.000	>10.000	no data available	no data available	no data available
Potassium chloride	2.600	no data available	no data available	no data available	no data available
Sodium azide	27	20	no data available	no data available	no data available

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation
- Remove exposed person to fresh air and keep warm and at rest in a position comfortable for breathing.

Skin
- Remove contaminated clothing and wash affected area with soap and water.

Eye
- In case of contact with eyes, irrigate with room-temperature water or eyewash solution for several minutes, occasionally lifting eyelids. Seek medical advice if irritation persists.

Ingestion
- If swallowed, rinse mouth thoroughly and give water to drink. **Do not induce vomiting.** Seek immediate medical attention if significant exposure is suspected, especially because of sodium azide content.

4.2 Most important symptoms and effects, both acute and delayed

- May cause irritation after contact with eyes, skin, or respiratory tract
- Harmful effects may occur if swallowed in significant quantity due to sodium azide content
- Contact with acids may release toxic gas

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptoms as they occur. Inform medical personnel that the product contains **sodium azide**.

SECTION 5: Firefighting measures

5.1 Extinguishing media	• **Suitable:** Use extinguishing media appropriate to cause of the fire, and the surroundings. Water spray, carbon dioxide and dry-chemical powder are suitable. • **Unsuitable:** Not available
5.2 Special hazards arising from the substance or mixture	• The product is a lyophilized powder, and is not classified as flammable. • Thermal decomposition may produce hazardous fumes. • Product contains sodium azide; toxic decomposition products may form under fire conditions. • Contact with acids may liberate toxic gas.
5.3 Advice for firefighters	• Firefighters should wear an approved self-contained breathing apparatus and full protective clothing

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures	• Avoid breathing dust. Ensure adequate ventilation. • Avoid contact with skin and eyes. Wear personal protection (suitable gloves and eye protection, see Section 8). • Product is supplied very small volumes (< 1 ml) in a glass vial, and does not pose a health or environmental hazard during foreseeable use. • Follow prescribed procedures for responding to large spills.
6.2 Environmental precautions	• Do not allow to enter drains, surface water, or soil. • **Important:** Do not flush into sinks connected to copper or lead plumbing.
6.3 Methods and material for containment and cleaning up	• Carefully collect spilled material to avoid dust formation. Place in suitable closed container for disposal. • Clean affected area with water after removal, while preventing uncontrolled discharge.
6.4 Reference to other sections	• For recommended personal protective equipment, see Section 8. • For disposal considerations, see Section 12.

SECTION 7: Handling and storage

7.1 Precautions for safe handling	• Use with adequate ventilation • Avoid creating dust • Avoid contact with skin, eyes, and clothing • Do not eat, drink, or smoke when using this product • Keep away from acids • Avoid disposal into metal plumbing systems containing copper or lead

7.2 Conditions for safe storage, including any incompatibilities	• Store tightly closed in original container • Store in a cool, dry, well-ventilated place • Protect from moisture • Keep away from acids • Store according to manufacturer's recommended temperature conditions
7.3 Specific end use(s)	• For laboratory/research use only. • Not for diagnostic or therapeutic use in humans or animals.

SECTION 8: Exposure control/personal protection

8.1 Control parameters

8.1 Control parameters	• No specific EU occupational exposure limit identified here for the mixture as such. • Follow good laboratory practice.
8.2 Exposure controls	• **Appropriate engineering controls:** Use in a fume hood or in areas with good general ventilation. • **Eye/face protection:** Safety glasses or chemical safety goggles • **Skin protection:** Protective laboratory gloves (e.g. nitrile) and Lab coat or suitable protective clothing • **Respiratory protection**: Normally not required under intended conditions of use. If dust is generated, use suitable particulate respiratory protection. • **Hygiene measures:** Wash hands after handling. Remove contaminated clothing and wash before reuse. • **Environmental exposure controls:** Prevent release to drains and the environment.

SECTION : Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Solid, powder
Colour	White
Odour	Odorless
Melting/freezing point	Not available
Boiling point or initial boiling point and boiling range	Not available
Flammability	Not available
Lower and upper explosion limit	Not available
Flash point	Not available
Auto-ignition temp.	Not available

Decomposition temp.	Not available
pH	Not available
Kinematic viscosity	Not available
Solubility	Freely soluble in water
Partition coeff. n-octanol/water (log value)	Not available
Vapour pressure	Not available
Density or rel. density	Not available
Relative vapour density	Not available
Particle characteristics	Not available

9.2 Other Information

Not expected to meet the criteria for classification as explosive or oxidising

Additional information: After reconstitution with water, sodium azide concentration is **< 0.1%**.

SECTION 10: Stability and reactivity

10.1 Reactivity	• Contains sodium azide. May react with acids to release toxic gas. May react with copper and lead to form metal azides.
10.2 Chemical stability	• Stable under ambient conditions
10.3 Possibility of hazardous reactions	• Reaction with acids may release hydrazoic acid • Reaction with copper or lead may form explosive metal azides
10.4 Conditions to avoid	• Avoid storage at temperatures above 25 °C. • Contact with acids
10.5 Incompatible materials	• Acids • Copper • Lead • Heavy metal salts
10.6 Hazardous decomposition products	• Nitrogen oxides and other hazardous fumes may be formed on decomposition or combustion.

SECTION 11: Toxicological information

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

Acute toxicity	• Based on available data, the classification criteria are not met. • The mixture contains sodium azide, which has harmonised classification **Acute Tox. 2 (H300)**

Skin corrosion/irritation	• Based on available data, the classification criteria are not met.
Serious eye damage/irritation	• Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	• Based on available data, the classification criteria are not met.
Germ cell mutagenicity	• Based on available data, the classification criteria are not met.
Carcinogenicity	• Based on available data, the classification criteria are not met.
Reproductive toxicity	• Based on available data, the classification criteria are not met.
STOT-single exposure	• Based on available data, the classification criteria are not met.
STOT-repeated exposure	• Based on available data, the classification criteria are not met.
Aspiration hazard	• Not applicable to solid lyophilised mixture.

11.2 Information on likely routes of exposure

Inhalation of dust, ingestion, skin contact, eye contact

11.3 Symptoms related to physical, chemical and toxicological characteristics

Possible irritation. Ingestion of substantial quantities may be harmful due to sodium azide.

SECTION 12: Ecological information

12.1 Toxicity	• No ecotoxicity test data are available for the mixture as such. • The mixture contains sodium azide, which has harmonised environmental classification **Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410)** • Sodium azide: LC50 (Lepomis macrochirus, 96 h), 0.7 mg/L; EC50 (Oncorhynchus mykiss, 96 h), 0.8 mg/L).
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	• No ingredient classified as PBT or vPvB.
12.6 Endocrine disrupting properties	• No ingredient classified for endocrine disrupting properties.
12.7 Other adverse effects	• Prevent release to drains and watercourses. • Because of sodium azide content, uncontrolled release should be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/container in accordance with local, regional, national, and international regulations.

Special disposal advice:

- Do not discharge into drains
- Do not dispose through plumbing systems containing copper or lead
- Collect waste for disposal as chemical waste

Contaminated packaging:

- Dispose of in accordance with applicable regulations.

SECTION 14: Transport information

14.1 UN Number	• Not classified as dangerous goods for transport.
14.2 UN proper shipping name	• Not regulated as dangerous goods based on current draft assessment.
14.3 Transport hazard class(es)	• Not assigned
14.4 Packing group	• Not assigned
14.5 Environmental hazards	• Not regulated as dangerous goods
14.6 Special precautions for user	• Protect from moisture. Avoid release of dust. Keep away from acids.
14.7 Maritime transport in bulk according to IMO instruments	• Not applicable

SECTION 15: Regulatory information

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

This Safety Data Sheet has been prepared in accordance with applicable requirements of Regulation (EC) No 1907/2006 (REACH), as amended, and Regulation (EC) No 1272/2008 (CLP), as amended.

Further national regulations may apply.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this mixture.

SECTION 16: Other info

16.1 Revisions	• This version 1.0 is formatted according to EU Regulation 2020/878.
16.2 References	• Search for chemicals; available at the European Chemicals Agency website: http://echa.europa.eu/.

16.3 Abbreviations and acronyms	• CLP: Classification, Labelling and Packaging Regulation • SDS: Safety Data Sheet • EUH: Supplemental hazard statement • PBT: Persistent, Bioaccumulative and Toxic • vPvB: very Persistent and very Bioaccumulative
16.3 Basis of classification	• The mixture is classified on the basis of available information on the ingredients.
16.4 List of hazard statements	• H300 - Fatal if swallowed • H400 - Very toxic to aquatic life • H410 - Very toxic to aquatic life with long lasting effects • EUH032 - Contact with acids liberates very toxic gas

Additional information

This product is supplied as a lyophilized mixture and is intended to be reconstituted with water before use.
After reconstitution with water, sodium azide concentration is **< 0.1%**.
This product is **not intended for diagnostic or therapeutic use in humans or animals**.

Disclaimer: The above information is believed to be correct but is only to be used as a guide for experienced personnel. Proteintech Group, Inc. shall not
be liable for any damage resulting from the handling of or contact with the above product.

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