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

1.1 Product identifier

- **Trade name:** Thymosin Alpha 1
- **Chemical Identification:** $C_{129}H_{215}N_{33}O_{55}$
- **Other chemical names:** Thymafalsin(e), Zadaxin
- **CAS Number:** 62304-98-7
- **EINECS Number:** -
- **Index number:** -
- **Registration number:** Registration number for this substance has not yet been assigned or the substance is manufactured / imported in a volume that does not require its registration.

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

- **Sector of Use:** SU24 Scientific research and development
- **Contents and application of the substance / mixture:** Raw material for research and development. (More information provided further on in the Safety Data Sheet)
    - **Not recommended uses**: All except above mentioned uses.

1.3 Details of the supplier of the safety data sheet

- **Manufacturer/Supplier:**

  Myotrope Peptides Inc.
  2598 E Sunrise Blvd #2104
  33304, Fort Lauderdale, FL
  United States
  E-mail: info@myotrope.com
  Tel: +1 954-872-0361

1.4 Emergency telephone number:

- **Poisons Centres in Europe (consultation in case of acute intoxication):**
  http://www.eapcct.org/index.php?page=links
  https://poisoncentres.echa.europa.eu/appointed-bodies

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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

- **Classification according to Regulation (EC) No 1272/2008**: The substance is not classified, according to the CLP regulation.
- **Additional information:** Although the product is not classified as dangerous, may show signs of danger (see sections 9-12 SDS).

2.2 Label elements

- **Labelling according to Regulation (EC) No 1272/2008:** Void
- **Hazard pictograms:** Void
- **Signal word:** Void
- **Hazard statements:** Void
- **Precautionary statements:** Void
- **Additional information:** There is no need to label the product in compliance with the directives of European Committee of national regulation/legislation.

2.3 Other hazards

- **Results of PBT and vPvB assessment**
- **PBT:** According to the information available, the product does not meet criteria such as PBT - persistent, bioaccumulative and toxic (substance on its own or in a mixture with concentration ≥ 0.1% by weight).
- **vPvB:** According to the information available, the product does not meet criteria such as vPvB - very persistent, very bioaccumulative (substance on its own or in a mixture with concentration ≥ 0.1% by weight).
- **Determination of endocrine-disrupting properties**: According to the information available, the product does not meet the criteria for having endocrine disrupting properties (substance on its own or in a mixture with concentration ≥ 0.1% by weight).

SECTION 3: Composition/information on ingredients

3.1 Substances

- **CAS No. Description**
  CAS: 62304-98-7
- **Additional information:**
  Formula: $C_{129}H_{215}N_{33}O_{55}$
  Sequence: Ac-Ser-Asp-Ala-Ala-Val-Asp-Thr-Ser-Ser-Glu-Ile-Thr-Thr-Lys-Asp-Leu-Lys-Glu-Lys-Lys-Glu-Val-Val-Glu-Glu-Ala-Glu-Asn
  Molecular weight: 3108.3 g/mol

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SECTION 4: First aid measures

4.1 Description of first aid measures

- **General information:** Use personal protective equipment. In case of any uncertainty or if any symptoms occur, seek medical assistance and show this SDS or label. Protect your health. Information for doctor: treatment is symptomatic.
- **After inhalation:** Supply fresh air; consult doctor in any case.
- **After skin contact:** Generally the product does not irritate the skin. Immediately rinse with water if contact occurs. Remove contaminated clothing. Seek medical help and show this SDS or label.
- **After eye contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical help and show this SDS or label.
- **After swallowing:** If swallowed wash out with plenty of water. Do not induce vomiting. Seek medical help and show this SDS or label.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- **Suitable extinguishing agents:** CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Cool container at risk with water jet spray. Fire-extinguishing activities according to surrounding

5.2 Special hazards arising from the substance or mixture: Under certain fire conditions, traces of other toxic gases cannot be excluded, e.g.:

5.3 Advice for firefighters

- **Protective equipment:**
  Do not stay in dangerous zone without self-contained breathing apparatus. Use chemical overall and equipment.
- **Additional information:**
  Cool container with spray water from a save distance. Contain escaping vapours with water. Prevent firefighting water from entering surface water or groundwater.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- **6.1.1 For non-emergency personnel:** Do not inhale dust. Ensure supply of fresh air in enclosed rooms. Avoid contact with eyes and skin.
- **6.1.2. For emergency responders:** More info in section 5.

6.2 Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Spilled product mechanically collect and then place in suitable containers. Follow disposal is governed by regulations set out in section 13, watch the value in section 8. The affected area and used tools thoroughly wash with suitable detergent, do not use solvents.

6.4 Reference to other sections:

See section 7 for information on safe handling. See section 8 for information on personal protective equipment. See section 13 for information on safe disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling:

Before the usage check out sections 2, 6, 8 and 11. Don't breathe aerosold/dust. Eating, drinking, smoking as well as food storage, is prohibited in work room.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
  Store at temperature -20 ^{0}C.
  Store only in the original properly sealed and marked containers.
- **Information about storage in one common storage facility:**
  Store away from foods/drinks.
  Do not store with incompatible materials (see section 10).
- **Further information about storage conditions:** None.

7.3 Specific end use(s):

Right usage of product is enclosed in product documentation or on label.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- **Ingredients with limit values that require monitoring at the workplace:**
  General maximum dust: <1 mg / m3 for respirable dust. Also see local regulations.

8.2 Exposure controls

- **8.2.2 Appropiate engineering controls:**
  The usual precautionary measures are to be adhered to when handling chemicals.
- **8.2.3 Individual protection measures, such as personal protective equipment:**
  General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.
- **8.2.4 Respiratory protection:**

Normally not needed. In case of insufficient ventilation, the creation of dust and excess of permitted exposure limits use appropriate respiratory mask with filter against solid aerosols.

Filter P (EN 14387).

- **8.2.5 Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and degradation.

Protective gloves (EN 374).

- **Material of gloves:**
  The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
  Nitrile rubber, NBR (EN 374). Recommended thickness of the material >0,5mm.
- **Penetration time of glove material:**
  The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **8.2.6 Eye/face protection:**

Safety goggles (EN 166).

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- **8.2.7 Skin protection / other protective measures:**

Protective clothing with long sleeves (EN ISO 6529) and safety shoes (EN ISO 20345, EN ISO 20346, or EN ISO 20347).

- **8.3 Environmental exposure controls:**
  Close the packaging properly after and during the work. Store containers stably. Avoid tipping over unsecured packaging. Clean contaminated packaging from contaminant.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

• **Physical state / appearance:**	Solid Powder
• Colour:	Undetermined.
• Odour:	Undetermined.
• Odour threshold:	Undetermined.
• pH-value:	Undetermined.
• Change in condition:	Undetermined.
• Melting point/freezing point:	Undetermined.
• Initial boiling point and boiling range:	Undetermined.
• Flash point:	Not applicable.
• Flammability (solid, gas):	Undetermined.
• Decomposition temperature:	Undetermined.
• Auto-ignition temperature:	Undetermined.
• Explosive properties:	Undetermined.
• Explosion limits:	Undetermined.
• Lower:	Undetermined.
• Upper:	Undetermined.
• Vapour pressure:	Undetermined.
• Density:	Undetermined.
• Relative density:	Undetermined.
• Vapour density:	Undetermined.
• Evaporation rate:	Undetermined.
• Solubility in / Miscibility with water:	Undetermined.
• Partition coefficient: n-octanol/water:	Undetermined.
• Viscosity:	Undetermined.
• Dynamic:	Undetermined.
• Kinematic:	Undetermined.

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9.2 Other information: No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity: No further relevant information available.
10.2 Chemical stability
Thermal decomposition / conditions to be avoided: See section 7
10.3 Possibility of hazardous reactions: No dangerous reactions known.
10.4 Conditions to avoid: No further relevant information available.
10.5 Incompatible materials: No further relevant information available.
10.6 Hazardous decomposition products: No further relevant information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- **Acute toxicity:**
  Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
  Based on available data, the classification criteria are not met.
- **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.

11.2 Additional toxicological information:

- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction):**
  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:**
  Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

12.1 Toxicity / Aquatic toxicity:
No further relevant information available.
12.2 Persistence and degradability:
No further relevant information available.
12.3 Bioaccumulative potential:
No further relevant information available.
12.4 Mobility in soil:
No further relevant information available.
12.5 Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.
12.6 Other adverse effects:
No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation:
Hand over the waste only to a person authorized for further waste disposal / processing according to the waste catalog. At compliance with all physico-chemical (and other) aspects of the nature of the waste respect the waste management hierarchy:

1. Prevention, 2. Reuse, 3. Material recovery (recycling), 4. Other uses (eg energy), 5. Disposal (eg landfilling - only for solid or stabilized liquid waste). See section 15 for waste disposal legislation.

European waste catalogue:
Catalogue numbers with an asterisk (*) indicate hazardous wastes (H), numbers without asterisk indicates non-hazardous waste (NH).

16 03 06	Organic wastes other than those mentioned in 16 03 05
15 01 02	Plastic packaging
20 01 39	Plastics

SECTION 14: Transport information

14.1 UN-Number:	-
ADR, ADN, IMDG, IATA	Void
14.2 UN proper shipping name:	-
ADR, ADN, IMDG, IATA	Void
14.3 Transport hazard class(es):	-
ADR, ADN, IMDG, IATA	Void
ADN/R Class	Void

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14.4 Packing group:	-
ADR, IMDG, IATA	Void
14.5 Environmental hazards:	-
Marine pollutant:	Not applicable.
14.6 Special precautions for user:	Not applicable.
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	-
	Not applicable
UN "Model Regulation":	Void

SECTION 15: Regulatory information

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

- **Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances.**
  Named dangerous substances - ANNEX I Substance is not listed.
- **Annex I - Restricted explosives precursors. (Upper limit value for the purpose of licensing under Article 5(3)).**
  Substance is not listed.
- **Annex II – Reportable explosives precursors.**
  Substance is not listed.
- **Regulation (EC) No 273/2004 on drug precursors.**
  Substance is not listed.
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.**
  Substance is not listed.

15.2 European legislation and regulatory information:

- REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (and subsequent amendments and supplements).
- REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (and subsequent amendments and supplements).
- COMMISSION REGULATION (EU) No 2020/878 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

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- Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.
- DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on waste and repealing certain Directives (and subsequent amendments and supplements).
- DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use (and subsequent amendments and supplements).
- REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (and subsequent amendments and supplements).
- REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Council Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 (and subsequent amendments and supplements).
- DIRECTIVE 2000/54/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (and subsequent amendments and supplements).
- REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (and subsequent amendments and supplements).
- REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products (and subsequent amendments and supplements).
- REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products (and subsequent amendments and supplements).
- COMMISSION IMPLEMENTING REGULATION (EU) 2021/128 of 2 February 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good manufacturing practice for veterinary medicinal products (and subsequent amendments and supplements).
- COMMISSION DELEGATED REGULATION (EU) 2023/1542 of 15 May 2023 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (and subsequent amendments and supplements).

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

16.1 Relevant phrases (for hazardous variants if applicable):

- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.

16.2 Abbreviations and acronyms:

- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- ATE: acute toxicity estimate
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- CLP – Classification, Labeling and Packaging of substances and mixtures (abreviation for Regulation 2008/1278/EC)
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- EL50: Effective Loading, 50 %
- ErC50 / EC50: value of the effective concentration of the test substance at which 50% of the test organisms die or immobilize
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- IATA: International Air Transport Association
- IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
- ICAO: International Civil Aviation Organization
- ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
- IMDG: International Maritime Code for Dangerous Goods
- LC50: lethal concentration that causes death in 50% of the test population
- LD50: lethal dose that causes death in 50% of the test population (median lethal dose)
- LL50: median lethal loading
- NLP: No-Longer Polymers
- NO(A)EL: dose value without observed adverse effect
- NOEC: highest concentration of the substance at which no adverse effects are observed
- NOELR: no-observable effect loading rate
- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
- SDS: Safety Data Sheet
- UFI: unique formula identifier (code according related toxicological center can identify the dangerous properties of the mixture from the label after poisoning)

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- VOC: Volatile Organic Compounds (USA, EU)
- TOC: Total Organic Compounds
- Vol %: volume percentage
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3