

Trade name:

Tesamorelin

Chemical name: Tesamorelin Acetate

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

1.1 Product identifier

Trade name: Tesamorelin

Chemical name: Tesamorelin Acetate

Other chemical names:

N-[trans-3-hexenoyl]-hGRF(1-44) amide — a synthetic growth-hormone-releasing factor (GRF) analogue (all 44 residues of human GHRH)

CAS Number: 218949-48-5

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

Application of the substance / mixture

Raw material for research and development. (see more labels, or product / data sheet)

Not recommended uses: All except above mentioned uses.

1.3 Details of the supplier of the safety data sheet

Manufacturer / Supplier:

ViraChem j.d.o.o.

Savska cesta 42

10000 Zagreb, Croatia

OIB: 73782597071 | MBS: 060500406

E-mail: info@virachemical.com

Web: virachemical.com

Further information obtainable from: info@virachemical.com

1.4 Emergency telephone number

Poisons Centres in Europe (consultation in case of acute intoxication):

<https://poisoncentres.echa.europa.eu/appointed-bodies>

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, it 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: EUH210 — Safety data sheet available on request.
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 $\geq 0.1\%$ 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 $\geq 0.1\%$ 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 $\geq 0.1\%$ by weight).

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances
CAS No.: 218949-48-5
Description: Tesamorelin Acetate
Additional information:
Sequence: YADAIFTNSYRKVLGQLSARKLLQDIMSRQQGESNQERGARARL-NH ₂ (one-letter code; all 44 residues of human GHRH / hGRF 1-44; N-terminus modified with a trans-3-hexenoyl group; C-terminal amide)
Molecular formula: C ₂₂₁ H ₃₆₆ N ₇₂ O ₆₇ S · xCH ₃ COOH
Molecular weight: 5135.86 g/mol (free base)

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures
General information:
Remove contaminated clothing and shoes. In case of any uncertainty or if symptoms occur, seek medical assistance and show this SDS or label. Protect your health. Treatment is symptomatic.
After inhalation: Ensure supply of fresh air. In the event of symptoms refer for medical treatment.
After skin contact: Wash off with soap and water. Remove contaminated clothing. Seek medical help if necessary.
After eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical help if necessary.
After swallowing: Wash out mouth with plenty of water. Do not induce vomiting. Call doctor immediately.
4.2 Most important symptoms and effects, both acute and delayed



No further relevant information available (for more see sections 2 and 11).

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:

Carbon dioxide, dry extinguisher, alcohol resistant foam (large fire). Cool container at risk with water jet spray. Fire-extinguishing activities according to surroundings.

Unsuitable extinguishing agents: Not determined.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire:

Carbon dioxide (CO₂)

Carbon monoxide (CO)

Nitrogen oxides (NO_x)

Sulfur oxides (SO_x)

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 safe distance. Contain escaping vapours with water. Prevent fire-fighting water from entering surface water or groundwater.

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 discharge into drains, surface waters or groundwater.

6.3 Methods and material for containment and cleaning up

Spilled product: mechanically collect and place in suitable containers. Disposal governed by regulations in section 13; see exposure values in section 8. Thoroughly wash affected area and used tools with suitable detergent — do not use solvents.

6.4 Reference to other sections

See section 7 for safe handling. | Section 8 for personal protective equipment. | Section 13 for safe disposal.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Before use, check sections 2, 6, 8 and 11. Do not breathe aerosol/dust. Eating, drinking and smoking, as well as food storage, are prohibited in the work room.

Fire and explosion protection: No special measures required.



7.2 Conditions for safe storage, including any incompatibilities

Storage requirements:

Store in a dry place. Protect against water and moisture.

Store only in the original, properly sealed and marked containers.

Store in accordance with requirements stated on the label / technical specification.

Temperature ranges:

-18 °C: 3 years

0 - 7 °C: 1 year

7 - 30 °C: 6 months

Common storage facility:

Store away from foodstuffs.

Do not store with incompatible materials (see section 10).

Further storage conditions: None.

7.3 Specific end use(s)

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

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Control parameters**General maximum dust: 10 mg/m³ for respirable dust. See local regulations.**8.2 Exposure controls****8.2.1 Appropriate engineering controls:**

The usual precautionary measures are to be adhered to when handling chemicals.

8.2.2 Individual protection measures — personal protective equipment:

Respiratory protection: Normally not needed. In case of insufficient ventilation or excess of permitted exposure limits, use appropriate respiratory mask with filter against solid aerosols. Filter P (EN 14387).

Hand protection: Protective gloves (EN 374) — Nitrile rubber, NBR. Recommended thickness: ≥ 0.4 mm. Penetration time: ≥ 480 min (EN 16523-1).

Eye / face protection: Wear closely fitting protective glasses with side protection (EN 166) in case of splashes.

Skin protection: Protective clothing with long sleeves (EN ISO 6529) and safety shoes (EN ISO 20345 / 20346 / 20347).

Thermal hazards: Void.

8.2.3 Environmental exposure controls:

Close packaging properly during and after work. Store containers stably. Avoid tipping over unsecured packaging. Clean contaminated packaging from contaminant.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid / Powder

Colour: No data available.

Odour: Not determined.

Odour threshold: Not determined.

Melting point / freezing point: Undetermined.

Boiling point / initial boiling point: Undetermined.



Flammability: Product is not flammable.
Lower explosion limit: Not determined.
Upper explosion limit: Not determined.
Flash point: Not applicable.
Auto-ignition temperature: Not determined.
Decomposition temperature: Not determined.
pH: Not applicable.
Kinematic viscosity: Not applicable.
Dynamic viscosity: Not applicable.
Solubility in water: Soluble in water and aqueous buffers; supplied as a lyophilised powder for reconstitution. No quantitative measured value available.
Partition coefficient n-octanol/water (log value): Not determined.
Vapour pressure: Not applicable.
Absolute density: Not determined.
Relative vapour density: Not applicable.
Particle characteristics: Not determined.
Explosive properties: Product does not present an explosion hazard.
VOC (EC): Not determined.
Evaporation rate: Not applicable.
Explosives: Void
Flammable gases: Void
Aerosols: Void
Oxidising gases: Void
Gases under pressure: Void
Flammable liquids: Void
Flammable solids: Void
Self-reactive substances and mixtures: Void
Pyrophoric liquids: Void
Pyrophoric solids: Void
Self-heating substances and mixtures: Void
Substances emitting flammable gas in contact with water: Void
Oxidising liquids: Void
Oxidising solids: Void
Organic peroxides: Void
Corrosive to metals: Void
Desensitised explosives: Void

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity: See section 10.3.

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: See section 5.

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes — Regulation (EC) No 1272/2008

Acute toxicity: Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

Caution! To the best of our knowledge the toxicological properties of this material have not been thoroughly investigated.

Primary irritant effect:

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.

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.

Respiratory/skin sensitisation: Based on available data, the classification criteria are not met.

STOT-single exposure: Criteria not met. Inhalation of dust can cause irritation of the respiratory tract.

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.

Ingestion: Abdominal discomfort and other negative effects (nausea, sickness etc.). Effects may be immediate or delayed.

Routes of exposure: See the above information in section 11.

Interactive effects: No data available.

Absence of specific data: No data available.

11.2 Information on other hazards

Endocrine disrupting properties: Substance is not listed.

Other information: See the above information in section 11.

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:

Caution! To the best of our knowledge the ecotoxicological properties of this material have not been thoroughly investigated.

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 Endocrine disrupting properties: The product does not contain substances with endocrine disrupting properties.
12.7 Other adverse effects
Not classified as hazardous for environment.
Do not allow product to reach groundwater, water courses or sewage systems, even in small quantities.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation:

Hand over waste only to a person authorised for waste disposal/processing according to the waste catalogue. Respect the waste management hierarchy: 1. Prevention 2. Reuse 3. Material recovery (recycling) 4. Other uses (e.g. energy) 5. Disposal (e.g. landfilling). See section 15 for waste disposal legislation.

European waste catalogue

16 03 06: Organic wastes other than those mentioned in 16 03 05

15 01 02: Plastic packaging

20 01 39: Plastics

Uncleaned packaging

Recommendation: Dispose as non-hazardous waste.

SECTION 14 TRANSPORT INFORMATION

14.1 UN number or ID number (ADR/RID/ADN, IMDG, IATA): Void

14.2 UN proper shipping name (ADR/RID/ADN, IMDG, IATA): Void

14.3 Transport hazard class(es): Void

14.4 Packing group (ADR/RID/ADN, IMDG, IATA): Void

14.5 Environmental hazards: Not applicable.

14.6 Special precautions for user: Not applicable.

14.7 Maritime transport in bulk (IMO instruments): Not applicable.

Transport / Additional information: Not dangerous according to the above specifications.

SECTION 15 REGULATORY INFORMATION

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

Directive 2012/18/EU — Major-accident hazards involving dangerous substances:

Named dangerous substances — ANNEX I: Substance is not listed.

Regulation (EU) 2019/1148 — Explosives precursors:

Annex I (Restricted): Substance is not listed.

Annex II (Reportable): Substance is not listed.

Regulation (EC) No 273/2004 — Drug precursors: Substance is not listed.

Regulation (EC) No 111/2005 — Drug precursors trade monitoring: Substance is not listed.

European legislation applicable

REGULATION (EC) No 1272/2008 (CLP) — Classification, labelling and packaging of substances and mixtures, and subsequent amendments.

REGULATION (EC) No 1907/2006 (REACH) — Registration, Evaluation, Authorisation and Restriction of Chemicals, and subsequent amendments.

COMMISSION REGULATION (EU) No 2020/878 — Amending Annex II to REACH.

Commission Regulation (EU) 2018/605 — Scientific criteria for endocrine disrupting properties.

DIRECTIVE 2008/98/EC — Waste framework directive, and subsequent amendments.

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

SECTION 16 OTHER INFORMATION

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

Training hints: Workers must be trained in accordance with local provisions.

Abbreviations and acronyms

ADR: Agreement concerning the International Carriage of Dangerous Goods by Road

ATE: Acute toxicity estimate

CAS: Chemical Abstracts Service

CLP: Classification, Labelling and Packaging — Regulation 1272/2008/EC

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

EL50: Effective Loading, 50%

ErC50/EC50: Effective concentration at which 50% of test organisms die or immobilise

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by IATA

ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods

LC50: Lethal concentration, 50% of test population

LD50: Lethal dose, 50% of 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 at which no adverse effects are observed

NOELR: No-observable effect loading rate

PBT: Persistent, Bioaccumulative and Toxic

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals — Reg. 1907/2006/EC

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

SDS: Safety Data Sheet

UFI: Unique Formula Identifier

vPvB: Very Persistent and Very Bioaccumulative

VOC: Volatile Organic Compounds

Vol %: Volume percentage

