

SAFETY DATA SHEET

Prepared in accordance with the requirements of Annex II to Regulation (EC) No 1907/2006 (REACH)

Date of preparation	2025-12-06
Revision date	2025-12-06
Trade name	SS-31

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

1.1 Product identifier

Trade name	SS-31
Chemical name	Elamipretide
CAS No.	736992-21-5
Registration number	Not provided.

A REACH registration number has not yet been assigned to this substance, or the substance is manufactured/imported in quantities for which registration under the REACH Regulation is not required.

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

Sector of use

SU24 - Scientific research and development.

Use of the substance/mixture

Raw material intended for scientific research and experimental development.

(Further information is provided on the product label or in the technical data sheet.)

Uses advised against

All uses other than those specified above.

1.3 Details of the supplier of the safety data sheet

Manufacturer / Supplier	UAB Advauto
Company code	306980920
VAT No.	LT100019954810
Address	Giedraičių g. 39, R53, LT-09302 Vilnius
Email	dovydasvoinickis@gmail.com

1.4 Emergency telephone number

Lithuanian Poison Information Centre: +370 5 236 2052

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

The substance is not classified as hazardous under Regulation (EC) No 1272/2008 (CLP).

Additional information

Although the product is not classified as hazardous, it may present hazards under certain conditions. Further information is provided in Sections 9-12 of this safety data sheet.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Hazard pictograms	Not applicable.
Signal word	Not applicable.
Hazard statements (H)	Not applicable.
Precautionary statements (P)	Not applicable.
Supplemental information	EUH210 - Safety data sheet available on request.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT

Based on the available information, the product does not meet the criteria for a PBT (persistent, bioaccumulative and toxic) substance, either as a pure substance or as a component of a mixture at a concentration of ≥ 0.1 % by weight.

vPvB

Based on the available information, the product does not meet the criteria for a vPvB (very persistent and very bioaccumulative) substance, either as a pure substance or as a component of a mixture at a concentration of ≥ 0.1 % by weight.

Endocrine-disrupting properties

Based on the available information, the product does not meet the criteria for endocrine-disrupting properties, either as a pure substance or as a component of a mixture at a concentration of ≥ 0.1 % by weight.

SECTION 3: Composition/information on ingredients

3.1 Substances

CAS No.	736992-21-5
Substance name	Elamipretide

Additional information

Amino acid sequence (peptide structure):

D-Arg-2',6'-dimethylTyr-Lys-Phe-NH₂

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

Immediately remove contaminated clothing and footwear (use appropriate personal protective equipment; see Section 8). If in doubt or if any symptoms occur, seek medical advice and present this safety data sheet or the product label. Protect the health and safety of the affected person.

Information for the physician: Treat symptomatically.

Following inhalation

Move the affected person to fresh air. If symptoms occur, seek medical advice.

Following skin contact

Wash the skin thoroughly with soap and water. Remove contaminated clothing. Seek medical advice if necessary.

Following eye contact

Immediately rinse the eyes thoroughly with plenty of water, including beneath the eyelids, for at least 15 minutes. Seek medical advice if necessary.

Following ingestion

If accidentally swallowed, rinse the mouth thoroughly and give plenty of water to drink. Do not induce vomiting. Seek medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information is available.

Additional information is provided in Sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information is available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

- Carbon dioxide (CO₂).
- Dry chemical powder.
- Alcohol-resistant foam (in the event of a large fire).

Cool containers exposed to fire with water spray. Use firefighting measures appropriate to the surrounding materials.

Unsuitable extinguishing media

Not determined.

5.2 Special hazards arising from the substance or mixture

Heating the product or exposure to fire may generate hazardous decomposition products and toxic gases, including:

- carbon dioxide (CO₂);
- carbon monoxide (CO);
- nitrogen oxides (NO_x).

5.3 Advice for firefighters

Special protective equipment for firefighters

Do not enter the hazardous area without self-contained breathing apparatus. Wear chemical-resistant protective clothing and appropriate personal protective equipment.

Additional information

Cool containers from a safe distance using water spray. Suppress released vapours with water mist. Prevent firefighting water from entering surface waters, groundwater or the sewer system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

- Do not breathe dust.
- Ensure adequate ventilation in enclosed areas.
- Avoid contact with eyes and skin.

6.1.2 For emergency responders

Additional information is provided in Section 5.

6.2 Environmental precautions

Prevent the product from entering sewer systems, surface waters or groundwater.

6.3 Methods and material for containment and cleaning up

Collect spilled product mechanically and place it in suitable waste collection containers.

Handle waste in accordance with the requirements of Section 13. Use the personal protective equipment specified in Section 8.

Thoroughly clean the contaminated area and used work equipment with a suitable cleaning agent. Do not use solvents.

6.4 Reference to other sections

For information on safe handling, see Section 7.

For information on personal protective equipment, see Section 8.

For information on waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Before using the product, review the information provided in Sections 2, 6, 8 and 11.

Do not breathe aerosols or dust.

Eating, drinking, smoking and storing food are prohibited in the workplace.

Fire and explosion protection measures

No special measures are required.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements for storage rooms and containers

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

Keep only in the original, properly labelled and tightly closed containers.

Store in accordance with the requirements stated on the manufacturer's or supplier's label and/or technical specification.

Recommended storage conditions

- -18 °C - up to 3 years.
- 0-7 °C - up to 1 year.
- 7-30 °C - up to 6 months.

Information on storage with other materials

Keep away from foodstuffs.

Do not store together with incompatible materials (see Section 10).

Additional information on storage conditions

No additional requirements.

7.3 Specific end use(s)

The intended purpose and appropriate use of the product are specified in the product documentation or on the label.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with occupational exposure limit values in the workplace

Maximum permissible concentration of respirable dust: 10 mg/m³.

Observe the applicable national legislation and occupational exposure limit values.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

When handling chemicals, standard occupational safety and hygiene requirements must be observed.

8.2.2 Individual protection measures, such as personal protective equipment

Respiratory protection

Respiratory protection is generally not required under normal conditions of use.

If ventilation is inadequate, dust is generated, or occupational exposure limits are exceeded, use a suitable respirator fitted with a P-class filter for protection against solid aerosols (EN 14387).

Hand protection

Use chemical-resistant protective gloves in accordance with EN 374.

Glove material	Nitrile rubber (NBR) (EN 374).
Recommended glove thickness	≥ 0.4 mm
Breakthrough time	≥ 480 min (EN 16523-1).

The glove material must be impermeable and resistant to this product. When selecting protective gloves, account must be taken of resistance to permeation, penetration and chemical degradation.

Depending on the conditions of use, the performance of protective gloves may vary; therefore, the glove manufacturer's recommendations must be followed.

The exact protection time is specified by the glove manufacturer and must be observed.

Skin protection / Other protective measures

Wear long-sleeved protective clothing meeting the requirements of EN ISO 6529 and protective footwear in accordance with EN ISO 20345, EN ISO 20346 or EN ISO 20347.

Thermal hazards

Not applicable.

8.2.3 Environmental exposure controls

Keep the packaging tightly closed during and after work.

Store containers securely to prevent tipping or accidental spillage.

Immediately clean any product residue from the outer surface of the packaging.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Property	Value
Physical state	Solid
Form	Powder
Colour	No data available
Odour	Not determined
Odour threshold	Not determined
Melting point/freezing point	Not determined
Boiling point or initial boiling point and boiling range	Not determined
Flammability	The product is non-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	No data available
Partition coefficient n-octanol/water (log K _{ow})	Not determined
Vapour pressure	Not applicable
Absolute density	Not determined
Relative vapour density	Not applicable
Particle characteristics	Not determined

9.2 Other information

Information with regard to physical hazard classes

Explosive properties

The product does not present an explosion hazard.

Volatile organic compounds (VOC)

Not determined.

Evaporation rate

Not applicable.

Physical hazard class	Classification
Explosives	Not applicable
Flammable gases	Not applicable
Aerosols	Not applicable

Physical hazard class	Classification
Oxidising gases	Not applicable
Gases under pressure	Not applicable
Flammable liquids	Not applicable
Flammable solids	Not applicable
Self-reactive substances and mixtures	Not applicable
Pyrophoric liquids	Not applicable
Pyrophoric solids	Not applicable
Self-heating substances and mixtures	Not applicable
Substances and mixtures which, in contact with water, emit flammable gases	Not applicable
Oxidising liquids	Not applicable
Oxidising solids	Not applicable
Organic peroxides	Not applicable
Corrosive to metals	Not applicable
Desensitised explosives	Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

See Section 10.3.

10.2 Chemical stability

Thermal decomposition and conditions to avoid

See Section 7.

10.3 Possibility of hazardous reactions

No hazardous reactions are known under normal conditions of use and storage.

10.4 Conditions to avoid

No further relevant information is available.

10.5 Incompatible materials

No further relevant information is available.

10.6 Hazardous decomposition products

See Section 5.

SECTION 11: Toxicological information

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

Acute toxicity

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

LD₅₀ / LC₅₀ values relevant for classification

Attention: Based on the available information, the toxicological properties of this substance have not been fully investigated.

Primary irritant effect

Skin corrosion/irritation

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

Serious eye damage/eye irritation

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

Germ cell mutagenicity

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

Carcinogenicity

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

Reproductive toxicity

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

Respiratory or skin sensitisation

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

Specific target organ toxicity (STOT) - single exposure

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

Inhalation of dust may irritate the respiratory tract.

Specific target organ toxicity (STOT) - repeated exposure

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

Aspiration hazard

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

Ingestion

Ingestion may cause abdominal discomfort and other adverse symptoms (e.g. nausea or general malaise). Effects may occur immediately or after a delay.

Information on mixtures/substances

Not applicable. The product is a substance, not a mixture.

Information on likely routes of exposure

See the information provided in this Section 11.

Symptoms related to the physical, chemical and toxicological characteristics

See the information provided in this Section 11.

Delayed and immediate effects as well as chronic effects from short- and long-term exposure

See the information provided in this Section 11.

Interactive effects

No data available.

Absence of specific data

No data available.

11.2 Information on other hazards**Endocrine-disrupting properties**

The substance is not included in lists of substances with endocrine-disrupting properties.

Other information

See the information provided in this Section 11.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Attention: Based on the available information, the ecotoxicological properties of this substance have not been fully investigated.

12.2 Persistence and degradability

No further relevant information is available.

12.3 Bioaccumulative potential

No further relevant information is available.

12.4 Mobility in soil

No further relevant information is available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendations

Waste must be transferred only to a waste operator authorised to carry out waste collection, treatment or disposal activities, in accordance with applicable legislation and the European Waste Catalogue.

When handling waste, the waste hierarchy must be observed and all physical, chemical and other properties of the waste must be taken into account:

- 1 Prevention of waste generation.
- 2 Preparation for reuse.
- 3 Recycling of materials.
- 4 Other recovery (e.g. energy recovery).
- 5 Disposal (e.g. landfill disposal - only for solid or stabilised liquid waste).

See Section 15 for legislation applicable to waste management.

European Waste Catalogue (EWC)

Waste codes marked with an asterisk (*) indicate hazardous waste; codes without an asterisk indicate non-hazardous waste.

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

Uncleaned packaging

Recommendations

Treat uncleaned packaging as non-hazardous waste in accordance with applicable waste management legislation.

SECTION 14: Transport information

14.1 UN number or ID number

Transport regulations	Data
ADR / RID / ADN	Not applicable
IMDG	Not applicable
IATA	Not applicable

14.2 UN proper shipping name

Transport regulations	Data
ADR / RID / ADN	Not applicable
IMDG	Not applicable
IATA	Not applicable

14.3 Transport hazard class(es)

Transport regulations	Hazard class
ADR / RID / ADN	Not applicable
IMDG	Not applicable
IATA	Not applicable
ADN/R	Not applicable

14.4 Packing group

Transport regulations	Data
ADR / RID / ADN	Not applicable
IMDG	Not applicable
IATA	Not applicable

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

Additional information

Under the requirements of ADR, RID, ADN, IMDG and IATA, the product is not classified as dangerous goods.

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

Annex I - Named dangerous substances: The substance is not listed.

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors

Annex I - Restricted explosives precursors (limit values for licensing purposes under Article 5(3)): The substance is not listed.

Annex II - Reportable explosives precursors: The substance is not listed.

Regulation (EC) No 273/2004 on drug precursors

The substance is not listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade in drug precursors between the European Union and third countries

The substance is not listed.

Applicable European Union legislation

- 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, as subsequently amended.
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 (REACH) concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, establishing a European Chemicals Agency (ECHA), as subsequently amended.
- Commission Regulation (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006 (REACH) as regards requirements for the compilation of safety data sheets.
- Commission Regulation (EU) 2018/605 concerning the scientific criteria for the determination of endocrine-disrupting properties.
- Directive 2008/98/EC of the European Parliament and of the Council on waste, as subsequently amended.

15.2 Chemical safety assessment

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

SECTION 16: Other information

The information contained in this safety data sheet is based on the knowledge available at the date of preparation. It does not constitute a guarantee of specific product properties and does not create any legally binding contractual obligations.

Worker training

Workers must be trained to handle the product in accordance with applicable national legislation and local occupational safety requirements.

Abbreviations and acronyms

Abbreviation	Meaning
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road.
ATE	Acute Toxicity Estimate.
CAS	Chemical Abstracts Service.
CLP	Classification, Labelling and Packaging Regulation.
EINECS	European Inventory of Existing Commercial Chemical Substances.
ELINCS	European List of Notified Chemical Substances.
EL ₅₀	Effective loading rate causing an effect in 50 % of the test organisms.
ErC ₅₀ / EC ₅₀	Effective concentration causing an effect in 50 % of the test organisms.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
IATA	International Air Transport Association.
IATA-DGR	International Air Transport Association Dangerous Goods Regulations.
ICAO	International Civil Aviation Organization.
ICAO-TI	International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air.
IMDG	International Maritime Dangerous Goods Code.
LC ₅₀	Concentration of a substance causing mortality in 50 % of the test organisms.
LD ₅₀	Dose of a substance causing mortality in 50 % of the test organisms (median lethal dose).
LL ₅₀	Median lethal loading rate.
NLP	No-Longer Polymers.
NO(A)EL	No Observed (Adverse) Effect Level.
NOEC	No Observed Effect Concentration.
NOELR	No Observed Effect Loading Rate.
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail.
SDS	Safety Data Sheet.
UFI	Unique Formula Identifier.
VOC	Volatile Organic Compounds.
TOC	Total Organic Carbon.
Vol. %	Volume percent.
PBT	Persistent, bioaccumulative and toxic substance.
vPvB	Very persistent and very bioaccumulative substance.