

SAFETY DATA SHEET

Safety data sheet according to (EC) No. 1907/2006.

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

1.1. Product identifier:

Exendin-4-Acetate (Exenatide)

CAS-no.: 141758-74-9

EC-no.: 686-356-3

INDEX-no.: None.

REACH-REG.-no.: None.

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

For medical and veterinary research and/or commercial use. Restricted to professional users.

1.3. Details of the supplier of the safety data sheet:

Polypeptide Laboratories Pvt Limited.

Addl. Ambarnath MIDC,

Ambarnath (E) 421506

1.4. Emergency telephone:

Telephone: + 91 251 3981900

Fax: + 91 251 3981925

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

Substance that may harm the unborn child. Suspected of causing cancer.

Exenatide is synthetic exenatide, which is a bioactive peptide with similar activities to glucagon-like-peptide 1 (GLP-1).

Special caution should always be taken in the handling of biologically active material or materials similar to those.

CLP (1272/2008): Carc. 2;H351 Repr. 2;H361d

2.2. Label elements:



WARNING

Content: Exenatide

H351: Suspected of causing cancer.

H361d: Suspected of damaging the unborn child

P201: Obtain special instructions before use.

P260: Do not breathe dust.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313: IF exposed or concerned: Get medical advice/attention.

P405: Store locked up.

2.3. Other hazards: Caution - substance not yet fully tested.

PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII.



SECTION 3: Composition/information on ingredients

3.1. Substances:

% w/w	Substance name	CAS-no.	EC-no.	Index-no.	REACH-reg.no.	Classification	Note
100	Exenatide	141758-74-9	686-356-3	-	-	Carc. 2;H351 Repr. 2;H361d	1

1) The substance is a polypeptide with the following sequence:

H-His-Gly-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Leu-Ser-Lys-Gln-Met-Glu-Glu-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu-Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH₂

Mol. Formula: C₁₈₄H₂₈₂N₅₀O₆₀S.

Wording of hazard statements - see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures:

Inhalation: Move the affected person to fresh air. Keep at rest. Seek medical advice.

Skin contact: Remove contaminated clothing and wash skin with water and mild soap. If irritation persists: Seek medical advice.

Eye contact: Flush with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. Seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed:

May cause nausea, vomiting and discomfort. May damage the unborn child. May cause cancer.

4.3. Indication of any immediate medical attention and special treatment needed:

Show this safety data sheet to a physician or emergency ward.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media:

Use water spray (never water jet), dry chemical, foam or carbon dioxide.

5.2. Special hazards arising from the substance or mixture:

Do not inhale smoke fumes. In case of fire, the substance may form hazardous decomposition products.

5.3. Advice for fire-fighters:

Use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment - see section 8. Avoid generation of dust and spreading. Ventilate area of leak or spill.

6.2. Environmental precautions:

Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.

6.3. Methods and material for containment and cleaning up:

Sweep up and place in a suitable container. Flush area of spill with plenty of water. Further handling of spillage - see section 13.

6.4. Reference to other sections:

See above



SECTION 7: Handling and storage

7.1. Precautions for safe handling:

Avoid breathing dust. Provide adequate ventilation e.g. by working in a fumehood. Do not open until use. Avoid contact with skin, eyes and clothing. Avoid generation of dust and spreading. Wash contaminated skin immediately with water and mild soap. Change contaminated clothing immediately. Take precautionary measures against static discharges.

Required access to water and eye wash fountain

7.2. Conditions for safe storage, including any incompatibilities:

Store in a tightly closed original container at $-20\pm 5^{\circ}\text{C}$ in a dry and well-ventilated place. Avoid exposure to light.

In, addition see manufacturer's specifications.

Store locked up, securely and out of reach of unauthorized personnel and separated from food, feed, drugs etc.

7.3. Specific end use(s):

See section 1.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters:

Sweden: AFS 2015:7: None

UK: Occupational exposure limits (EH40/2005 with later amendments): None.

Exanatide $0,5 \mu\text{g}/\text{m}^3$ (Astra Zeneca OEL):

DNEL/PNEC: No CSR.

8.2. Exposure controls:

Appropriate engineering controls: Provide adequate ventilation e.g. by working in a fume hood.

Personal protective equipment:

Respiratory protection: During all open handling use an approved mask (EN149) with a particle filter type P3. The filter has a limited lifetime and must be changed. Read the instruction.

Skin protection: Wear protective gloves (EN374) of e.g. nitrile rubber. It has not been possible to find any data for breakthrough time, so it is recommended to change the glove if spilled on.

Eye protection: Wear tightly fitting safety goggles (EN166) in case of risk of contact with the eyes.

Environmental exposure controls: None particular.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Appearance:	White to off-white powder.
Odour:	No available data
Odour threshold:	No available data
pH (aqueous solution):	No available data
Melting point/freezing point ($^{\circ}\text{C}$):	No available data
Initial boiling point and boiling range ($^{\circ}\text{C}$):	Not applicable
Flash point ($^{\circ}\text{C}$):	Not applicable
Evaporation rate:	Not applicable
Flammability (solid, gas):	No available data
Upper/lower flammability or explosive limits (vol.-%):	No available data
Vapour pressure:	Not applicable
Relative density:	No available data
Solubility (water):	25 g/l
Partition coefficient: n-octanol/water:	No available data
Auto-ignition temperature ($^{\circ}\text{C}$):	No available data
Decomposition temperature ($^{\circ}\text{C}$):	No available data
Viscosity:	Not applicable
Explosive properties:	Dust may form explosive mixture with air.
Oxidising properties:	No available data
9.2. Other information:	Molecular weight: 4186.6 g/mol



SECTION 10: Stability and reactivity

10.1. Reactivity:

No available information.

10.2. Chemical stability:

Stable under normal conditions - see section 7. Combustible.

10.3. Possibility of hazardous reactions:

Dust may form explosive mixture with air.

10.4. Conditions to avoid:

Avoid sparks, embers, heating and direct sunlight. Avoid generation of dust.

10.5. Incompatible materials:

Bases and oxidizing agents

10.6. Hazardous decomposition products:

When heated to high temperatures (decomposition) toxic fumes are emitted.

SECTION 11: Toxicological information

11.1. Information on toxicological effects:

No available/applicable toxicological data.

Information on likely routes of exposure: Inhalation, skin and ingestion.

Symptoms

Inhalation: Exenatide stimulates secretion of insulin. May cause headache, nausea, vomiting, diarrhoea and nasopharyngitis.

Skin: May cause slight irritation.

Eyes: May cause irritation.

Ingestion: See under "Inhalation".

Chronic effects: May cause cancer. May harm the unborn child. Peptides may cause potential antigenicity and allergic reactions. Special caution should always be taken in the handling of polypeptides with hormone-like effects.

SECTION 12: Ecological information

12.1. Toxicity:

No available/applicable data.

12.2. Persistence and degradability:

No available/applicable data.

12.3. Bioaccumulative potential:

No available/applicable data.

12.4. Mobility in soil:

No available/applicable data.

12.5. Results of PBT and vPvB assessment:

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

12.6. Other adverse effects:

None

known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods:

Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.

EWC-code

07 05 99



SECTION 14: Transport information

Not hazardous for transportation (ADR/RID/IMDG/IATA)

14.1. UN-no.: None

14.2. UN proper shipping name: None

14.3. Transport hazard class(es): None

14.4. Packing group: None

14.5. Environmental hazards: None.

14.6. Special precautions for user: None.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code: Not relevant

SECTION 15: Regulatory information

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

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions (Directive 92/85/EEC).

Must not be used by persons under 18 years of age.

15.2. Chemical Safety Assessment:

No CSR.

SECTION 16: Other information

Hazard statements mentioned in section 2 and 3:

H351: Suspected of causing cancer.

H361d: Suspected of damaging the unborn child

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC₅₀ = Effect Concentration 50 %

FW = Freshwater

LC₅₀ = Lethal Concentration 50 %

LD₅₀ = Lethal Dose 50 %

PBT = Persistent, Bioaccumulative, Toxic

PNEC = Predicted No-Effect Concentration

vPvB = very Persistent, very Bioaccumulative

Literature:

ECHA = REACH Registration dossier from ECHA's homepage.

EPA Ecotox = Environmental Protection Agency

IUCLID = International Uniform Chemical Database Information

RTECS = Register of Toxic Effects of Chemical Substances

<http://pro.medicin.dk>

Training advice:

No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.

Additional information:

The information presented herein is believed to be accurate and representative of currently accepted technical literature.

However, PolyPeptide Laboratories does not mean to imply its completeness or comprehensiveness. Therefore, we suggest the use of this information solely as a guide in the use and handling of this product, and further urge the user to determine the suitability of this material for any particular purpose. PolyPeptide Laboratories shall not be held liable for any damages resulting from sole reliance on this information Changes since the previous edition:

Section 1 and 7. Minor changes in section 1-16

