

## 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:

Leuprolide Acetate  
CAS-no.: 74381-53-6  
EC-no.: 686-285-8  
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 ltd.  
Plot No.K-28,  
Addl. Ambernath MIDC,  
Ambernath (E).

Responsible person for the safety data sheet (e-mail): ppl@polypeptide.com

## 1.4. Emergency telephone:

Telephone: + 91 251 3981900112  
Fax : + 91 251 3981925

**SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture:

Harmful substance that may impair fertility and harm the unborn child. May cause sensitization by inhalation and skin contact.

Leuprorelin acetate is an analogue of gonadorelin, which is the synthetic form of GnRH (hypothalamic gonadotropin-releasing hormone in man).

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

CLP (1272/2008): Skin Sens. 1;H317 Acute Tox. 4;H332 Resp. Sens. 1;H334 Repr. 1A;H360

## 2.2. Label elements:

Restricted to professional users.



DANGER

Contains: Leuprorelin acetate

H317: May cause an allergic skin reaction.

H332: Harmful if inhaled.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H360: May damage fertility or the unborn child

P201: Obtain special instructions before use.

P260: Do not breathe dust.

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

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

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

P405: Store locked up.

## 2.3. Other hazards: None known.

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



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## SECTION 3: Composition/information on ingredients

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## 3.1. Substances:

% w/w	Substance name	CAS	EC-no.	Index-no.	REACH reg.no.	Classification
100	Leuprorelin acetate	74381-53-6	686-285-8	-	-	Skin Sens. 1;H317 Acute Tox. 4;H332 Resp. Sens. 1;H334 Repr. 1A;H360

Wording of hazard statements - see section 16

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## SECTION 4: First-aid measures

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## 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:

Bone pain, hot flushes, headache and gastro-intestinal disturbance. Leuprorelin impairs fertility and harm the unborn child. It may cause reduced libido. May cause asthma symptoms and allergic skin reaction.

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

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

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## SECTION 5: Fire-fighting measures

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## 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 product may form hazardous decomposition: Carbon- and nitrogen oxides.

## 5.3. Advice for fire-fighters:

Use breathing apparatus with an independent source of air.

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## SECTION 6: Accidental release measures

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## 6.1. Personal precautions, protective equipment and emergency procedures:

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

## 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.

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## SECTION 7: Handling and storage

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## 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 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.



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**SECTION 8: Exposure controls/Personal protection**


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## 8.1. Control parameters:

Sweden: AFS 2015:7: None

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

DNEL/PNEC: No CSR.

## 8.2. Exposure controls:

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

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.

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**SECTION 9: Physical and chemical properties**


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## 9.1. Information on basic physical and chemical properties:

Appearance:	White powder
Odour:	No available data
Odour threshold:	No available data
pH (aqueous solution)	No available data
Melting point/freezing point (°C):	No available data
Initial boiling point and boiling range (°C):	Not applicable
Flash point (°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):	Soluble
Partition coefficient: n-octanol/water:	No available data
Auto-ignition temperature (°C):	No available data
Decomposition temperature (°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:	None relevant

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**SECTION 10: Stability and reactivity**


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## 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:

Strong heat, light and moisture. Avoid generation of dust.

## 10.5. Incompatible materials:

Bases and strong acids.

## 10.6. Hazardous decomposition products:

When heated to high temperatures (decomposition) toxic fumes are emitted: Carbon- and nitrogen oxides.



## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects:

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	No available/applicable data.	-	-
Dermal	No available/applicable data.	-	-
Oral	LD <sub>50</sub> (rat) = >3000 mg/kg (gonadorelin acetate)	No info	RTECS
Corrosion/irritation:	No available/applicable data.	-	-
Sensitization:	No available/applicable data.	-	-
CMR:	TD <sub>Lo</sub> (female rats, i.v.) = 0.54 mg/kg, 17-22D after conception; "Effects on newborn" (Gonadorelin diacetate)	No info	RTECS
	TD <sub>Lo</sub> (female rats, i.v.) = 26 mg/kg, 6-18D after conception; Maternal/reproductive effects/fertility" (Gonadorelin diacetate)	No info	RTECS

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

#### Symptoms:

- Inhalation:** Harmful by inhalation. Inhalation of dust has several effects on the gonads. Symptoms may include bone pain, headache, gastro-intestinal disturbances, ovulation, increased menstrual bleeding and hot flushes.
- Skin:** May cause irritation.
- Eyes:** May cause irritation.
- Ingestion:** See under "Inhalation"
- Chronic effects:** Gonadotropins may impair fertility and the unborn child. It may cause changes in sex hormones, reduced libido and abortion. Gonadorelin is also found to cause osteoporosis. 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.



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## SECTION 15: Regulatory information

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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.

Please contact national authorities regarding notification and use of the substance (Directive 2001/82/EC).

Leuprolide is on WADA's list of prohibited doping substances (The World Anti-Doping Code): Group S2, PEPTIDE HORMONES, GROWTH FACTORS, RELATED SUBSTANCES, AND MIMETICS; Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) and their releasing factors.

15.2. Chemical Safety Assessment:

No CSR.

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## SECTION 16: Other information

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Hazard statements mentioned in section 2 and 3:

H360: May damage fertility or the unborn child

H317: May cause an allergic skin reaction.

H332: Harmful if inhaled.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC<sub>50</sub> = Effect Concentration 50 %

FW = Freshwater

LC<sub>50</sub> = Lethal Concentration 50 %

LD<sub>50</sub> = 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

