

SAFETY DATA SHEET

1. PRODUCT

1.1 Product identifiers

Name: Leuprolide acetate salt

CAS-No.: 74381-53-6

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

Identified uses : Laboratory chemicals, Manufacture of substances

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture.

2.2 GHS Label elements, including precautionary statements

Not a hazardous substance or mixture.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS

No data available

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms: des-Gly10-[D-Leu6]-LH-RH ethylamide
Leuprorelin

Formula: $C_{59}H_{84}N_{16}O_{12} \cdot xC_2H_4O_2$

CAS-No.: 74381-53-6

Hazardous components

Component	Classification	Concentration
Leuprolide acetate salt		-

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice
Move out of dangerous area.
If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration.
In case of skin contact
Wash off with soap and plenty of water.
In case of eye contact
Flush eyes with water as a precaution.
If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.2 Indication of any immediate medical attention and special treatment needed

no data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, nitrogen oxides (NO_x)

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing vapours, mist or gas.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: -20 °C

Keep in a dry place.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

General industrial hygiene practice.

Personal protective equipment

Eye/face protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Body Protection	Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection	Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure	Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Form: powder Colour: white
Odour	no data available
Odour Threshold	no data available
pH	no data available
Melting point/freezing point	no data available
Initial boiling point and boiling range	no data available
Flash point	no data available
Evaporation rate	no data available
Flammability (solid, gas)	no data available
Upper/lower flammability or explosive limits	no data available
Vapour pressure	no data available
Vapour density	no data available
Relative density	no data available
Water solubility	no data available
Partition coefficient: n-octanol/water	no data available
Auto-ignition temperature	no data available
Decomposition temperature	no data available
Viscosity	no data available
Explosive properties	no data available
Oxidizing properties	no data available

9.2 Other safety information

no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

no data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Other decomposition products - no data available

In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity
LD50 Oral - rat - > 5,000 mg/kg Inhalation: no data available Dermal: no data available no data available
Skin corrosion/irritation
no data available
Serious eye damage/eye irritation
no data available
Respiratory or skin sensitisation
no data available
Germ cell mutagenicity
no data available
Carcinogenicity
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH. NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
Reproductive toxicity
no data available Reproductive toxicity - rabbit - Subcutaneous Effects on Fertility: Post-implantation mortality (e.g., dead and/or resorbed implants per total number of implants). Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Reproductive toxicity - rat - Subcutaneous Paternal Effects: Testes, epididymis, sperm duct. Paternal Effects: Prostate, seminal vesicle, Cowper's gland, accessory glands. Reproductive toxicity - rat - Subcutaneous Paternal Effects: Testes, epididymis, sperm duct. Paternal Effects: Other effects on male. Reproductive toxicity - rat - Subcutaneous Effects on Fertility: Pre-implantation mortality (e.g., reduction in number of implants per female; total number of implants per corpora lutea). Effects on Newborn: Sex ratio. May cause reproductive disorders. no data available Developmental Toxicity - rat - Subcutaneous Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Specific Developmental Abnormalities: Musculoskeletal system.
Specific target organ toxicity -single exposure
no data available
Specific target organ toxicity -repeated exposure
no data available
Aspiration hazard
no data available
Additional Information

RTECS: OH6390000

May have actions similar to luteinizing hormone releasing hormone (LH-RH) and gonadotropin releasing hormone (GN-RH) which are the key mediators in the neuroregulation of the secretion of gonadotropins, luteinizing hormone (LH) and follicle stimulating hormone (FSH). LH-RH can modify sexual behavior by regulating plasma gonadotropin and sex steroid levels., To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

no data available

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

no data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.
Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

15. REGULATORY INFORMATION

SARA 302 Components

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

Chronic Health Hazard

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

Component	CAS-No.	Revision Date
Leuprolide acetate salt	74381-53-6	

New Jersey Right To Know Components

Component	CAS-No.	Revision Date
Leuprolide acetate salt	74381-53-6	

California Prop. 65 Components

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Component	CAS-No.	Revision Date
Leuprolide acetate salt	74381-53-6	1997-08-26

16. OTHER INFORMATION

HMIS Rating

Health hazard: 0

Chronic Health Hazard: *

Flammability: 0

Physical Hazard 0

NFPA Rating

Health hazard: 0

Fire Hazard: 0

Reactivity Hazard: 0
