

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Leuprolide acetate salt

Product Number : L0399
Brand : Sigma

Company : Sigma-Aldrich
3050 Spruce Street
SAINT LOUIS MO 63103
USA

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2. COMPOSITION/INFORMATION ON INGREDIENTS

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

Formula : C₅₉H₈₄N₁₆O₁₂ · xC₂H₄O₂

Molecular Weight : 1,209.4 g/mol

CAS-No.	EC-No.	Index-No.	Concentration
Leuprolide acetate salt			
74381-53-6	-	-	-

3. HAZARDS IDENTIFICATION**Emergency Overview****OSHA Hazards**

Reproductive hazard

HMIS Classification

Health Hazard: 0

Chronic Health Hazard: *

Flammability: 0

Physical hazards: 0

NFPA Rating

Health Hazard: 0

Fire: 0

Reactivity Hazard: 0

Potential Health Effects**Inhalation**

May be harmful if inhaled. May cause respiratory tract irritation.

Skin
Eyes
Ingestion

May be harmful if absorbed through skin. May cause skin irritation.
May cause eye irritation.
May be harmful if swallowed.

4. 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.

5. FIRE-FIGHTING MEASURES

Flammable properties

Flash point no data available

Ignition temperature no data available

Suitable extinguishing media

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

Special protective equipment for fire-fighters

Wear self contained breathing apparatus for fire fighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Avoid dust formation.

Environmental precautions

Do not let product enter drains.

Methods for cleaning up

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

7. HANDLING AND STORAGE

Handling

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Storage

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

Recommended storage temperature: -20 °C

Keep in a dry place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

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).

Hand protection

Handle with gloves.

Eye protection

Safety glasses with side-shields conforming to EN166

Hygiene measures

General industrial hygiene practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	powder
Colour	white

Safety data

pH	no data available
Melting point	no data available
Boiling point	no data available
Flash point	no data available
Ignition temperature	no data available
Lower explosion limit	no data available
Upper explosion limit	no data available
Water solubility	no data available

10. STABILITY AND REACTIVITY

Storage stability

Stable under recommended storage conditions.

Materials to avoid

Strong oxidizing agents

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NO_x)

11. TOXICOLOGICAL INFORMATION

Acute toxicity

LD50 Oral - rat - > 5,000 mg/kg

Irritation and corrosion

no data available

Sensitisation

no data available

Chronic exposure

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.

Developmental Toxicity - rat - Subcutaneous

Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Specific Developmental Abnormalities: Musculoskeletal system.

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.

Signs and Symptoms of Exposure

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.

Potential Health Effects

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Skin	May be harmful if absorbed through skin. May cause skin irritation.
Eyes	May cause eye irritation.
Ingestion	May be harmful if swallowed.

Additional Information

RTECS: OH6390000

12. ECOLOGICAL INFORMATION

Elimination information (persistence and degradability)

no data available

Ecotoxicity effects

no data available

Further information on ecology

no data available

13. DISPOSAL CONSIDERATIONS**Product**

Observe all federal, state, and local environmental regulations. 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**OSHA Hazards**

Reproductive hazard

DSL Status

All components of this product are on the Canadian DSL list.

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

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New Jersey Right To Know Components

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Revision Date

California Prop. 65 Components

WARNING! This product contains a chemical known in the State of California to cause birth defects or other reproductive harm.
Leuprolide acetate salt

CAS-No.
74381-53-6

Revision Date
1997-08-26

16. OTHER INFORMATION

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Co., shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.