

## SAFETY DATA SHEET

Version 3.8  
Revision Date 07/01/2014  
Print Date 11/10/2018

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1. PRODUCT AND COMPANY IDENTIFICATION

## 1.1 Product identifiers

Product name : Leuprolide acetate salt

Product Number : L0399

Brand : Sigma

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

## 1.3 Details of the supplier of the safety data sheet

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

Telephone : +1 800-325-5832

Fax : +1 800-325-5052

## 1.4 Emergency telephone number

Emergency Phone # : +1-703-527-3887 (CHEMTREC)

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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 - none

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3. COMPOSITION/INFORMATION ON INGREDIENTS

## 3.1 Substances

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

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

Molecular Weight : 1,209.40 g/mol

CAS-No. : 74381-53-6

## Hazardous components

Component	Classification	Concentration
Leuprolide acetate salt		-

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## 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

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

no data available

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## 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<sub>x</sub>)

### 5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

### 5.4 Further information

no data available

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## 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.

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## 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

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## 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.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

- |                                                 |                               |
|-------------------------------------------------|-------------------------------|
| a) Appearance                                   | Form: powder<br>Colour: white |
| b) Odour                                        | no data available             |
| c) Odour Threshold                              | no data available             |
| d) pH                                           | no data available             |
| e) Melting point/freezing point                 | no data available             |
| f) Initial boiling point and boiling range      | no data available             |
| g) Flash point                                  | no data available             |
| h) Evaporation rate                             | no data available             |
| i) Flammability (solid, gas)                    | no data available             |
| j) Upper/lower flammability or explosive limits | no data available             |
| k) Vapour pressure                              | no data available             |
| l) Vapour density                               | no data available             |
| m) Relative density                             | no data available             |

- |    |                                        |                   |
|----|----------------------------------------|-------------------|
| n) | Water solubility                       | no data available |
| o) | Partition coefficient: n-octanol/water | no data available |
| p) | Auto-ignition temperature              | no data available |
| q) | Decomposition temperature              | no data available |
| r) | Viscosity                              | no data available |
| s) | Explosive properties                   | no data available |
| t) | Oxidizing properties                   | no data available |

## **9.2 Other safety information**

no data available

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## **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

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## **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.

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## **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

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## 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.

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## 14. TRANSPORT INFORMATION

#### DOT (US)

Not dangerous goods

#### IMDG

Not dangerous goods

#### IATA

Not dangerous goods

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## 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

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

#### New Jersey Right To Know Components

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

#### California Prop. 65 Components

	CAS-No.	Revision Date
WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.	74381-53-6	1997-08-26

Leuprolide acetate salt

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## 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

**Further information**

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**Preparation Information**

Sigma-Aldrich Corporation  
Product Safety – Americas Region  
1-800-521-8956

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