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## PRODUCT AND COMPANY IDENTIFICATION

**GHS Product Name:** Leuprolide acetate

**Product code:** p-101

**Company:** PharmSintez.Lab

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### 1.1 Product identifiers

Product name:	Leuprolide acetate
Product Catalogue Number:	p-101
Band:	PharmSintez.Lab
CAS-No:	74381-53-6

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

Identified uses:	Laboratory chemicals, Synthesis of substances.
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## 1. IDENTIFICATION OF SUBSTANCE/PREPARATION AND THE COMPANY UNDERTAKING

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## 2. HAZARDS IDENTIFICATION

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**Classification:**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008 or GHS.  
Not a hazardous substance or mixture according to EC-Directives 67/548/EEC or 1999/45/EC.

**Labelling and precautionary statements:**

The product does not need to be labeled in accordance with EC directives or respective national laws.

**Hazard statement(s):** - Not required.

**Precautionary statement(s):** - Not required.

**Hazard symbol(s):** - Not required.

**R-phrases:** - Not required.

**S-phrases(s):** - Not required.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

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Molecular Formula: $C_{61}H_{88}N_{16}O_{14}$	Molecular weight: 1269.45	CAS Number: 74381-53-6	EINECS Number: -
Synonyms:	6-D-Leucine-9-(N-ethyl-L-prolinamide)-10-deglycinamideluteinizing hormone-releasing factor acetate		

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### 4. FIRST AID MEASURES

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Eye contact:	Immediately flush eye with copious amounts of water for at least 15 minutes. Get medical aid immediately.
Skin contact:	In case of contact remove contaminated clothing and immediately wash affected areas with copious quantities of water and soap for at least 15 minutes. Get medical aid immediately. Wash contaminated clothing before reuse.
Inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration. If breathing is difficult give oxygen. Get medical aid.
Ingestion:	Do NOT induce vomiting unless advised to do so by a physician or Poison Control Center. Never give anything by mouth to an unconscious person. Wash out mouth with water provided person is conscious. Call a physician.
Notes to Physician:	Treat symptomatically and supportively.

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### 5. FIRE-FIGHTING MEASURES

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Personal precautions:	As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.
Extinguishing media:	In case of fire use water spray, dry chemical, carbon dioxide, or alcohol-resistant foam.
Special hazards arising from the substance or mixture:	Carbon oxides, nitrogen oxides (NOx).

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### 6. ACCIDENTAL RELEASE MEASURES

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General Information:	Use proper personal protective equipment as indicated in Section 8.
Personal precautions:	Wear self-contained breathing apparatus, eye protection and gloves. Keep personal hygiene. Avoid contact with skin and eyes. Avoid dust formation. Avoid breathing dust, vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.
Environmental precautions:	Do not let product enter the drains. Prevent further leakage or spillage if safe to do so.
Spills/Leaks:	Sweep up and place the material in appropriate container for disposal without creating dust and dispose of as hazardous waste. Ventilate area, clean up spills and wash spill site after material pickup is complete, observing precautions in the Protective Equipment section.

## 7. HANDLING AND STORAGE

Handling:	Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Avoid contact with eyes, skin, and clothing. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
Storage:	Store in a cool, dry, well-ventilated area. Keep container tightly closed. Store under inert atmosphere. Refrigerate. Keep cold. Store at 2-8°C.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

### Personal protection equipment:

Eye protection:	Wear appropriate protective eyeglasses <sup>0</sup> with side-shields conforming to EN 166, chemical safety goggles or face-shield (min. 8-inch) as described by OSHA's eye and face protection regulations. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection:	Must wear appropriate protective gloves to prevent skin exposure, as defined in EU Directive 89/686/EEC and the standard EN 374 derived from it.
Body protection:	Appropriate protective clothing, overalls.
Respiratory protection:	Where risk assessment indicates air-purifying respirators are required use a dust mask type N95 (US) or type P1 (EN 143) respirator. Respirators and components must be tested and approved under appropriate government standards - NIOSH (US) or CEN (EU).
Hygiene measures:	Use good working practices. Wash hands and face thoroughly after handling.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

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Appearance:	White to off-white solid.
Odour:	Data not available/does not apply.
Odour threshold:	Data not available/does not apply.
pH:	Data not available/does not apply.
Melting point:	150 - 155°C (dec.)
Boiling point:	Data not available/does not apply.
Flash point:	Data not available/does not apply.
Evaporation rate:	Data not available/does not apply.
Flammability:	Data not available/does not apply.
Flammability or explosive limits:	Data not available/does not apply.
Vapor pressure:	Data not available/does not apply.
Vapor density:	Data not available/does not apply.
Sensity:	Data not available/does not apply.
Solubility:	Slightly soluble (DMSO, methanol).
Partition coefficient: n-octanol/water	Data not available/does not apply.
Auto-ignition temperature:	Data not available/does not apply.
Decomposition temperature:	Data not available/does not apply.
Viscosity:	Data not available/does not apply.

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## 10. STABILITY AND REACTIVITY

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Chemical stability:	Stable under recommended storage conditions.
Conditions to avoid:	Data not available.
Incompatibilities with other materials:	Strong oxidizing agents.
Hazardous decomposition products:	Carbon oxides, nitrogen oxides (NOx).
Hazardous polymerization:	Data not available.

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## 11. TOXICOLOGICAL INFORMATION

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<b>RTCS #:</b>	OH6390000.
<b>Acute toxicity:</b>	LD50 Oral: rat: > 5000 mg/kg.
<b>Skin corrosion/irritation:</b>	Data not available.
<b>Serious eye damage/eye irritation:</b>	Data not available.
<b>Respiratory or skin sensitization:</b>	Data not available.

<b>Germ cell mutagenicity:</b>	Data not available.
<b>Carcinogenicity: IARC:</b>	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.
<b>Reproductive toxicity:</b>	Limited laboratory results have shown reproductive toxicity/teratogenicity in animal models.
<b>Specific target organ toxicity - single exposure:</b>	Data not available.
<b>Specific target organ toxicity - repeated exposure:</b>	Data not available.
<b>Aspiration hazard:</b>	Data not available.
<b>Signs and symptoms of exposure:</b>	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.
<b>Potential health effects:</b>	
Eye:	May cause eye irritation.
Skin:	May be harmful by skin absorption. May cause skin irritation.
Ingestion:	May be harmful if swallowed.
Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Chronic:	No information found.

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## 12. ECOLOGICAL INFORMATION

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Data not available.

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## 13. DISPOSAL CONSIDERATIONS

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Observe all federal, state and local environmental regulations. Product may be burned in an incinerator equipped with afterburner and scrubber. Product is not to be disposed of in sanitary sewers, storm sewers, or landfills. Contact a licensed professional waste disposal service to

dispose of this material.

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#### 14. TRANSPORT INFORMATION

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**ADR/RID**

Not classified as hazardous for transport.

**IMDG**

Not classified as hazardous for transport.

**IATA**

Not classified as hazardous for transport.

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**Further  
information**

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**Preparation  
Information**

PharmSintez.Lab

Product Safety –  
multiple

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