

**Section 1: Identification**

**Product Name** LEUPROLIDE ACETATE USP  
**Commercial Name** Leuprorelin Acetate  
**Product Use** For medical and veterinary research and/or commercial use.  
**Restrictions On Use** Restricted to professional users  
**Product Code** 30-4535  
**Company** PCCA  
9901 South Wilcrest  
Houston, TX 77099  
Phone: 1-800-331-2498  
Fax: 1-800-874-5760

In case of emergency contact:  
**CHEMTREC (24hr) 1-800-424-9300**

**Section 2: Hazard(s) Identification**

**OSHA Haz Com:** Harmful substance that may impair fertility and harm the unborn child. May cause sensitization by inhalation and skin contact.  
**CFR 1910.1200**  
**Signal Word** DANGER  
**Hazard Statement(s)** MAY CAUSE ALLERGIC SKIN REACTION. HARMFUL IF INHALED. MAY CAUSE ALLERGY OR ASTHMA SYMPTOMS OR BREATHING DIFFICULTIES IF INHALED. MAY CAUSE DAMAGE TO FERTILITY OR UNBORN CHILD.

**Pictogram(s) or Symbol(s)****Precautionary Statement(s):**

**Prevention** Obtain special instructions before use. Do not breathe dust. Wear protective gloves/protective clothing/eye protection/face protection.  
**Response** May cause an allergic skin reaction. Harmful if inhaled. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May damage fertility or the unborn child. If inhaled: remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. If exposed or concerned: Get medical advice/attention.  
**Storage** Store locked up.  
**Disposal** Not available

**Section 3: Composition/Information on Ingredients**

**Substance/Mixture** Substance  
**Components** Leuprolide Acetate  
**% By Weight** 100  
**CAS#** 74381-53-6  
**Molecular Weight** 1269.4 g/mol  
**Chemical Formula** C61H88N16O14  
**Synonym(s)** Leuprorelin Acetate

Mixtures Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Leuprolide Acetate	74381-53-6	100	Not available	Not available

**Section 4: First-Aid Measures**

<b>Inhalation</b>	Move the affected person to fresh air. Keep at rest. Seek medical advice.
<b>Skin Contact</b>	Remove contaminated clothing and wash skin with water and mild soap. If irritation persists: Seek medical Advice.
<b>Eye Contact</b>	Flush water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.
<b>Ingestion</b>	Rinse mouth and drink plenty of water. Seek medical advice.
<b>Symptoms/Effects</b>	
<b>Acute</b>	Bone pain, hot flushes, headached 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.
<b>Delayed</b>	Bone pain, hot flushes, headached 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.

**Immediate Medical Attention**

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

**Section 5: Fire-Fighting Measures****Suitable Extinguishing Media**

Use water spray (never water jet), dry chemical, foam or carbon dioxide.

**Unsuitable Extinguishing Media**

Water jet

**Products of Combustion**

Carbon- and nitrogen oxides

**Firefighters Special Equipment and Precautions**

Use breathin apparatus with an independent source of air.

**Section 6: Accidental Release Measures**

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment - see section 8. Avoid generation of dust. Ventilate area of leak. Environmental precautions: Do not empty into drains - see section 12. Inform appropriate authorities in accordance with local regulations. 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.

**Section 7: Handling and Storage**

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 mil soap. Change contaminated clothing immediately. Take precautionary measures against static discharges. Required access to water and eye was fountain. Conditions for safe storage, including any incompatibilities: Store at -20+/-5°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.

**Section 8: Exposure Controls/Personal Protection**

<b>Exposure Limits</b>	None.
<b>Engineering Controls</b>	Appropriate engineering controls: Provide adequate ventilation e.g. by working in a fumehood.
<b>Personal Protection</b>	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.

**Section 9: Physical and Chemical Properties**

<b>Appearance</b>	White powder		
<b>Odor</b>	No available data		
<b>Odor Threshold</b>	Not available.		
<b>Melting Point</b>	Not available.	<b>pH</b>	Not available.
<b>Freezing Point</b>	Not available.	<b>Vapor Pressure</b>	Not available.
<b>Boiling Point/Range</b>	Not available.	<b>Vapor Density</b>	Not available.
<b>Decomposition temperature</b>	Not available.	<b>Viscosity</b>	Not available.
<b>Partition Coefficient: n-octanol/water</b>	Not available	<b>Evaporation Rate</b>	Not available.
<b>Flash Point</b>	Not available.	<b>Autoignition temperature</b>	Not available.
<b>Flammability</b>	Not available.	<b>Flammability or Explosive Limits:</b>	
		<b>Lower</b>	Not available.
		<b>Upper</b>	Not available.
<b>Solubility(ies)</b>	Soluble in water		
<b>Other</b>	Dust may form explosive mixture with air.		

**Section 10: Stability and Reactivity**

<b>Reactivity</b>	No available information
<b>Chemical Stability</b>	Stable under normal conditions - see section 7. Combustible.
<b>Hazardous Polymerization</b>	Dust may form explosive mixture with air.
<b>Conditions to Avoid</b>	Strong heat, light and moisture. Avoid generation of dust.
<b>Incompatible Materials</b>	Bases and strong acids.
<b>Hazardous Decomposition Products</b>	When heated to high temperatures (decomposition) toxic fumes are emitted: Carbon- and nitrogen oxides.

**Section 11: Toxicological Information**

<b>RTECS</b>	Not available.
<b>Acute Toxicity</b>	Acute toxicity LD50 Oral - rat - > 5.000 mg/kg
<b>Skin Corrosion/Irritation</b>	May cause skin irritation.
<b>Serious Eye Damage/Irritation</b>	May cause irritation.
<b>Respiratory or Skin Sensitization</b>	May cause irritation. 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.
<b>Germ Cell Mutagenicity</b>	Not available.
<b>Carcinogenicity</b>	Not available.
<b>Reproductive Toxicity</b>	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.

**Routes of Entry**

Likely routes of exposure: Inhalation, skin and ingestion.

**Symptoms Related to Exposure**

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.

**Potential Health Effects**

May cause irritation. May cause irritation. 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. 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.

**Target Organ(s)** Not available.

**Section 12: Ecological Information****Ecotoxicity**

Not available.

**Persistence and Degradability**

Not available.

**Bioaccumulative Potential**

Not available.

**Mobility in Soil**

Not available.

**Other Adverse Effects**

Not available.

**Section 13: Disposal Considerations****Waste Disposal**

Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.

**Disposal of Container**

Not available.

**Other Considerations**

Not available.

**Section 14: Transport Information****DOT Classification**

Not hazardous for transportation.

**Section 15: Regulatory Information****Regulations**

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.

**Other**

N/A

**Section 16: Other Information**



## Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

LEUPROLIDE ACETATE USP

30-4535

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Hazard statements mentioned in section 2 and 3: May damage fertility or the unborn child. May cause an allergic skin reaction. Harmful if inhaled. May cause allergy or asthma symptoms or breathing difficulties if inhaled. 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.