

**Product Name:** Leuprolide Acetate

**Issued:** Dec-18-2012

## **SAFETY DATA SHEET**

### **Section 1. Identification of the substance/mixture and of the company/undertaking**

#### **1.1 Product Identifier**

**Product Name:** Leuprolide Acetate

**Synonyms:** 6-D-Leucine-9-(N-ethyl-L-prolinamide)-10-deglycinamideluteinizing Hormone-releasing Factor Monoacetate; Leuprorelin, EP; Leuprolide Acetate Powder; Leuprolide Acetato; Acetato de Leuprolide

**List Number:** 5375; 5508; 3626

**Drug Code Number:** 41558; 16070; 53963

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

**Recommended use:** Pharmaceuticals

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

**Supplier:** AbbVie Inc.  
1 North Waukegan Road  
North Chicago, IL 60064  
USA  
1-800-255-5162  
+1-847-937-7433

**Customer Service Telephone:** 1-800-255-5162 (US and Canada only)  
+1-847-937-7433

**E-mail Address:** AbbVie.SDS@abbvie.com

#### **1.4 Emergency telephone number**

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)  
or +1-703-527-3887 (international)

### **Section 2. Hazards identification**

#### **2.1 Classification of the substance or mixture**

**Regulation (EC) No 1272/2008**

**Reproductive toxicity** Category 1B

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**

**Risk Phrases:** R60 - May impair fertility  
R61 - May cause harm to the unborn child

#### **2.2 Label elements**

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## Section 2. Hazards identification



**Signal Word:** Danger

**Hazard Statements:** H360 - May damage fertility or the unborn child

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P405 - Store locked up

P501 - Dispose of contents/container to an approved waste disposal plant

### 2.3 Other hazards

Not determined

## Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Leuprolide Acetate 74381-53-6	Proprietary	NA	R60, R61	Repr. 1B (H360)	No data available

Not Hazardous\* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**For the full text of the R-phrases mentioned in this Section, see Section 16**

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

## Section 4. First aid measures

### 4.1 Description of first aid measures

**Eye Contact:** Remove from source of exposure. Flush eyes with copious amounts of water. Seek immediate medical attention. Provide symptomatic/supportive care as necessary. Monitor hormone/sexual function as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. Seek immediate medical attention. Provide symptomatic/supportive care. Monitor hormone/sexual function as necessary.

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<b>Inhalation:</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Monitor hormone/sexual function as necessary.
<b>Ingestion:</b>	Remove from source of exposure. If signs of toxicity, occur seek medical attention. Provide symptomatic/supportive care as necessary. Monitor hormone/sexual function as necessary.
<b>Protection of First-aiders:</b>	Use personal protective equipment

#### **4.2 Most important symptoms and effects, both acute and delayed**

<b>Signs and Symptoms:</b>	None known from occupational exposure. Clinical data suggests the following: variable sex hormone level changes. Clinical signs may include, feeling hot, edema, gastrointestinal upset, dizziness, headaches, bone and joint pain, weakness.
<b>Medical Conditions Aggravated by Exposure:</b>	None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: ovaries, testes, urinary bladder. Pregnancy.

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

<b>Notes To Physician:</b>	Treat symptomatically
<b>Additional Information:</b>	Leuprolide Acetate : The initial response to leuprolide acetate is an increase in luteinizing hormone (LH), follicle stimulating hormone (FSH), and male and female sex hormones (e.g., testosterone and estrogens). Continued use leads to reductions in these hormones to castrate or post-menopausal levels.

### **Section 5. Firefighting measures**

#### **5.1 Extinguishing Media**

<b>Suitable Extinguishing Media:</b>	Use extinguishing agent suitable for type of surrounding fire
<b>Unsuitable Extinguishing Media:</b>	Not determined

#### **5.2 Special hazards arising from the substance or mixture**

<b>Special Exposure Hazards:</b>	Not determined
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#### **5.3 Advice for firefighters**

<b>Protective Equipment and Precautions for Firefighters:</b>	As in any fire, wear self-contained breathing apparatus and full protective gear
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### **Section 6. Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

<b>Personal Precautions:</b>	Avoid contact with the skin and the eyes.
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#### **6.2. Environmental precautions**

<b>Environmental Precautions:</b>	Contain material and prevent release to waterways or soil.
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### **6.3. Methods and material for containment and cleaning up**

**Methods for Cleaning Up:** Use large, disposable absorbant paper towels moistened with 10% (v/v) bleach to collect spilled product and clean the affected area.

### **6.4. Reference to other sections**

Refer to Sections 8, 12, and 13 for further information.

## **Section 7. Handling and storage**

### **7.1. Precautions for safe handling**

Handle in accordance with good industrial hygiene and safety practice.

### **7.2. Conditions for safe storage, including any incompatibilities**

Store according to label instructions

### **7.3. Specific end use(s)**

**Recommended use:** Pharmaceuticals

## **Section 8. Exposure controls/personal protection**

### **8.1. Control parameters**

#### **Exposure limits:**

<b>Chemical Name</b>	<b>Employee Exposure Limit</b>	<b>Skin Notation</b>
Leuprolide Acetate 74381-53-6	0.05 mcg/m <sup>3</sup>	None

### **8.2. Exposure controls**

**Engineering Controls:** Use inside a hood, glovebox or process enclosure.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Wear eye protection appropriate to exposures when handling the product formulation.

**Gloves:** Impervious gloves.

**Other PPE Data:** Wear appropriate body coverings if contact may occur.

**Environmental Exposure Controls:** Not determined

## **Section 9. Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

**Product Name:** Leuprolide Acetate

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<b>Appearance:</b>	White to off-white Powder
<b>Odor:</b>	Not determined.
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	5.5-7.5
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined.
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Not determined.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	Not determined.
<b>Vapor Density (Air = 1):</b>	Not determined.
<b>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Soluble in: water.
<b>Partition coefficient: n-octanol/water</b>	Not determined.
<b>Autoignition Temp. (°C):</b>	Not determined.
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Viscosity (centipoise):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	Not determined.

## **9.2. Other information**

Not determined

## **Section 10. Stability and reactivity**

### **10.1. Reactivity**

Not determined

### **10.2. Chemical stability**

Stable under normal conditions

### **10.3. Possibility of hazardous reactions**

**Hazardous reactions:** Not determined.

### **10.4. Conditions to avoid**

Not determined.

### **10.5 Incompatible materials**

Hypochlorite Solutions

### **10.6 Hazardous decomposition products**

Carbon oxides, Nitrogen oxides (NO<sub>x</sub>)

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## Section 11. Toxicological information

### 11.1. Information on toxicological effects

**Routes of Exposure:**

**Oral:** Not determined.

**Dermal:** Not determined.

**Inhalation:** Not determined.

**Acute Toxicity - Oral:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Leuprolide Acetate 74381-53-6	LD50 >	5000	mg/kg	Mice Rats

**Acute Toxicity - Dermal:** Not determined.

**Acute Toxicity - Inhalation:** Not determined.

**Other Toxicology Data:** Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Leuprolide Acetate	LD 50 (sc) >	5	mg/kg	Rats Mice	Highly Toxic
74381-53-6	LD 50 (im) >	2	mg/kg	Rats Mice	

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Not determined.

**Reproductive Effects:** In animals adverse reproductive effects include: embryo toxicity, fetal abnormalities.  
In clinical use adverse reproductive effects include: reduced fertility in males.  
Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Leuprolide Acetate 74381-53-6	Rabbits	0.1	mcg/kg	Subcutaneous	During Gestation

**Carcinogenicity:** Confirmed animal carcinogen with unknown relevance to humans  
Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Leuprolide Acetate	Pituitary gland	Rats	0.6	Subcutaneous	mg/kg/day	2 years
74381-53-6	No tumors	Mice	60			

Tumors were benign.

**Mutagenicity:** Not determined.

**Aspiration hazard:** Not determined

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**Notes:**

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

## **Section 12. Ecological information**

### **12.1. Toxicity**

Not determined.

### **12.2. Persistence and degradability**

Not determined.

### **12.3. Bioaccumulative potential**

Not determined

### **12.4. Mobility in soil**

Not determined.

### **12.5. Results of PBT or vPvB assessment**

Chemical safety report is not required for this substance/product.

### **12.6. Other adverse effects**

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**Notes:**

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

## **Section 13. Disposal considerations**

### **13.1 Waste treatment methods**

**Waste Disposal Methods:** Disposal should be made in accordance with country, federal, state and local regulations.

## **Section 14. Transport information**

### **ADR, DOT, ICAO/IATA, IMDG/IMO**

**Status:** Not regulated

- |                                    |                |
|------------------------------------|----------------|
| <b>14.1. UN Number:</b>            | Not applicable |
| <b>14.2. Proper shipping name:</b> | Not applicable |
| <b>14.3. Hazard class:</b>         | Not applicable |
| <b>14.4. Packing group:</b>        | Not applicable |
| <b>14.5. Environmental hazard:</b> | Not applicable |

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**14.6. Special Provisions:** Not applicable

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable

## Section 15. Regulatory Information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Leuprolide Acetate 74381-53-6	-	-	X	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Leuprolide Acetate 74381-53-6	-	-	-	-	-	

#### Legend

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**ISHL** - Japan Industrial Safety and Health Law

**IECSC** - China Inventory of Existing Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

#### Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Leuprolide Acetate	Proprietary	Not Listed	Not Listed	Not Listed

#### SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Leuprolide Acetate	Proprietary	No	Not Applicable	Not applicable

**Immediate Health:** Yes

**Delayed Health:** No

**Fire:** No

**Sudden Pressure:** No

**Reactivity:** No

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

**WHMIS Hazard Class:** D1A VERY TOXIC MATERIALS.



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**NFPA Rating:**

Health: 1

Fire: 1

Reactivity: 0

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

**15.2. Chemical safety assessment**

Chemical safety assessment has not been conducted on the substance/product.

**Section 16. Other information**

**Risk Phrases:** R60 - May impair fertility, R61 - May cause harm to the unborn child

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**Supersedes the SDS dated:** Apr-02-2009

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