

Product Name: Lupron Depot
Issued: Apr-08-2015



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Lupron Depot

Synonyms: Leuprolide Acetate Injection; Lupron Depot PED, 7.5 mg; Lupron Depot PED, 11.25 mg; Lupron Depot PED, 15 mg; Lupron Depot, 3.75 mg; Lupron Depot, 11.25 mg; Lupron Depot 7.5 mg; Lupron Depot, 3 month, 22.5 mg; Lupron Depot, 30 mg; Lupron Depot PED, 11.25 mg, 3 month; Lupron Depot PED, 3 month, 30 mg; Leuprolide Acetate Prefilled Dual Chamber Syringe (PDS), 45 mg; Leuprorelin Vial, 11.25 mg; Leuprolide Acetate Depot, 22.5 mg vial; Leuprorelin Prefilled Dual-chambered Syringe, 3.75 mg; Leuprorelin Prefilled Dual-chambered Syringe, 11.25 mg; Leuprorelin Vial, 3.75 mg; Leuprorelin Acetate Prefilled Dual-chambered Syringe, 3.75 mg; Leuprorelin Acetate Prefilled Dual-chambered Syringe, 30 mg; Leuprolide Acetate Depot PDS 30 mg 6 Months; Leuprolide Vial, 3.75 mg; Lupron Depot 6 Month 45 mg PDS Kit; Lupron Depot PDS Kit; Lupron Depot PED PDS Kit; Lucrin Depot Kit

Trade name: Lupron; Lucrin; Lupaneta Pack

List Number: Prefilled Syringe: 3154; 3306; 3330; 3132; 3662; 3152; 3338; 3680; 3779; 9694; 10511; M316; M346; M920; M922; M923; M924; M925; T016; T017; T052; G752
Kits: 3473; 3641; 3642; 2108; 2282; 2440; 3346; 3663; 3683; G754
Lupaneta Pack kits: 1052; 1053

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
+1-847-932-7900

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

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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



Signal Word: Danger

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

Precautionary Statements
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.
Polymers of lactic and glycolic acid	30-80	NA		Not Hazardous*	No data available
Mannitol 69-65-8	10-60	Present		Not Hazardous*	No data available
Leuprolide Acetate 74381-53-6	1-15	NA	R60, R61	Repr. 1B (H360)	No data available
Stearic Acid 57-11-4	0-5	Present		Not Hazardous*	No data available
Carboxymethylcellulose Sodium 9004-32-4	1-5	NA		Not Hazardous*	No data available
Gelatin 9000-70-8	0-5	Present		Not Hazardous*	No data available
Polysorbate 80 9005-65-6	0.1-1	NA		Not Hazardous*	No data available
Water 7732-18-5	0-1	Present		Not Hazardous*	No data available

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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 with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: 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.

Medical Conditions Aggravated by Exposure: Data suggest any pre-existing ailments in the following organs: ovaries, testes, urinary bladder.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: 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

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Wash spill area with 10% (v/v) bleach, then clean using a detergent solution followed by clean water.

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

Avoid contact with skin, eyes and clothing. 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:

Chemical Name	Employee Exposure Limit	Skin Notation
Polymers of lactic and glycolic acid	Not Applicable	None
Mannitol 69-65-8	Not Applicable	None
Leuprolide Acetate 74381-53-6	0.05 mcg/m ³	None
Stearic Acid 57-11-4	Not Applicable	None
Carboxymethylcellulose Sodium 9004-32-4	Not Applicable	None
Gelatin 9000-70-8	Not Applicable	None
Polysorbate 80 9005-65-6	Not Applicable	None
Water 7732-18-5	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
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Stearic Acid 57-11-4	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				
Carboxymethylcellulose Sodium 9004-32-4	10 mg/m ³ total dust; 3 mg/m ³ respirable dust				

8.2. Exposure controls

Engineering Controls:	No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.
Respiratory Protection:	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
Eyes:	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
Gloves:	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
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

Appearance:	Syringe powder chamber: White Powder Opaque Syringe liquid chamber: Clear Colorless Solution
Odor:	Not determined.
Odor Threshold:	Not determined
pH:	5-7 for the reconstituted product.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	Not determined.
Solubility(ies):	Not determined.
Partition coefficient: n-octanol/water	Not determined.
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	Not determined.
Viscosity (centipoise):	Not determined.
Explosion Severity:	Not determined.
Oxidizer Properties:	Not determined.

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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

Not determined

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: No
Dermal: Unlikely
Inhalation: No

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

Chemical Name	Acute Test	Value	Units	Species
Mannitol 69-65-8	LD50 =	13,500-22,000	mg/kg	Mice Rats
Leuprolide Acetate 74381-53-6	LD50 >	5000	mg/kg	Mice Rats
Stearic Acid 57-11-4	LD50 >	4640	mg/kg	Rats
Carboxymethylcellulose Sodium 9004-32-4	LD50 =	19000 27000	mg/kg	Guinea Pigs Mice Rabbits
Polysorbate 80 9005-65-6	LD50 =	25,000 - 36,570	mg/kg	Mice Rats

The clinical routes of administration for Lupron Depot are either intramuscular (IM) or subcutaneous (SC).

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

Chemical Name	Acute Test	Value	Units	Species
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Stearic Acid 57-11-4	LD50 >	5000	mg/kg	Rabbits
Carboxymethylcellulose Sodium 9004-32-4	LD50 >	2000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Carboxymethylcellulose Sodium 9004-32-4	LC 50 >	5800	mg/m ³	Rats

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

Chemical Name	Test Type	Value	Units	Species	Comments
Leuprolide Acetate 74381-53-6	LD 50 (sc) >	5	mg/kg	Rats Mice	Highly Toxic
	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: Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Mannitol 69-65-8	Eyes Kidney	Rats Mice	25,000	ppm	Oral Diet	Repeat dose study (ies).

Reproductive Effects: Lupron Depot is contraindicated by the FDA on women who are or may become pregnant. FDA interpreted a teratology study in rabbits as positive while Takeda and Abbott interpreted the study as negative. Treatment up to 3 years with doses as high as 10 mg/day or for 2 years with doses as high as 20 mg/day, resulted in no pituitary abnormalities. No adverse reactions had been reported in the workplace during 5 years due to potential exposure to leuprolide as documented by Abbott in 2001. As little as 10 mcg has been reported to stimulate an increase in LH and 100 mcg increased FSH in human females in a single-dose Phase I study.

Carcinogenicity: Active ingredient : In animals produced tumors in the following tissue (s): pituitary gland.
 NOEL = 60 mg/kg/day for tumor production in mice with no evidence for tumor production in mice dosed subcutaneously. Data for component(s) given below.

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

Mutagenicity: Negative in the Ames assay. No adverse effects on bone marrow chromosomes in an in vivo cytogenetic study in rats dosed subcutaneously and 4 mg/kg or lower. Negative in a dominant lethal assay in mice at subcutaneous dosages of 4 mg/kg or lower.

Aspiration hazard: Not determined

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

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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

14.1. UN Number: Not applicable

14.2. Proper shipping name: Not applicable

14.3. Hazard class: Not applicable

14.4. Packing group: Not applicable

14.5. Environmental hazard: Not applicable

14.6. Special Provisions: Not applicable

14.7. Transport in bulk Not applicable

**according to Annex II of
MARPOL 73/78 and the IBC**

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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
Polymers of lactic and glycolic acid	-	-	-	Not listed.	-
Mannitol 69-65-8	Present	X	X	Not listed.	X
Leuprolide Acetate 74381-53-6	-	-	X	Not listed.	-
Stearic Acid 57-11-4	Present	X	X	Not listed.	X
Carboxymethylcellulose Sodium 9004-32-4	-	X	X	Not listed.	X
Gelatin 9000-70-8	Present	X	X	Not listed.	X
Polysorbate 80 9005-65-6	-	X	X	Not listed.	X
Water 7732-18-5	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Polymers of lactic and glycolic acid	-	-	-	-	-	
Mannitol 69-65-8	Present	Present	X	X	Present	
Leuprolide Acetate 74381-53-6	-	-	-	-	-	
Stearic Acid 57-11-4	Present	-	X	X	Present	
Carboxymethylcellulose Sodium 9004-32-4	Present	Present	X	X	Present	HSR003136
Gelatin 9000-70-8	Present	-	X	X	Present	
Polysorbate 80 9005-65-6	Present	Present	X	X	Present	
Water 7732-18-5	-	2-(4)-1220	X	X	Present	

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:
Polymers of lactic and glycolic acid	30-80	Not Listed	Not Listed	Not Listed
Mannitol	10-60	Not Listed	Not Listed	Not Listed
Leuprolide Acetate	1-15	Not Listed	Not Listed	Not Listed
Stearic Acid	0-5	Not Listed	Not Listed	Not Listed
Carboxymethylcellulose Sodium	1-5	Not Listed	Not Listed	Not Listed
Gelatin	0-5	Not Listed	Not Listed	Not Listed

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Polysorbate 80	0.1-1	Not Listed	Not Listed	Not Listed
Water	0-1	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):
Polymers of lactic and glycolic acid	30-80	No	Not Applicable	Not applicable
Mannitol	10-60	No	Not Applicable	Not applicable
Leuprolide Acetate	1-15	No	Not Applicable	Not applicable
Stearic Acid	0-5	No	Not Applicable	Not applicable
Carboxymethylcellulose Sodium	1-5	No	Not Applicable	Not applicable
Gelatin	0-5	No	Not Applicable	Not applicable
Polysorbate 80	0.1-1	No	Not Applicable	Not applicable
Water	0-1	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: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Component	Percent	Proposition 65 Listed Materials
Leuprolide Acetate 74381-53-6 (1-15)	1-15	developmental toxicity, initial date 8/26/97 male reproductive toxicity, initial date 8/26/97 female reproductive toxicity, initial date 8/26/97

WHMIS Hazard Class: Not determined.

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

Full text of H-Statements referred to under sections 2 and 3
 H360 - May damage fertility or the unborn child

Document Authored By: Occupational and Environmental Toxicology

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Supersedes the SDS dated: Aug-08-2011

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