

Product Name:
Issued:

Lupron (R) Depot
Apr-06-2009



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories
1401 N. Sheridan Rd.
North Chicago, IL 60064
USA

Customer Service Telephone: 1 - 800 - 255 - 5162

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

Product Name: Lupron (R) Depot

Synonyms: Lupron Depot-PED- 7.5 mg
Lupron Depot-PED 11.25 mg
Lupron Depot-PED 15 mg
Lupron Depot 3.75 mg
Lupron Depot - 3 month 11.25 mg
Lupron Depot 7.5 mg
Lupron Depot - 3 month 22.5 mg
Lupron Depot - 4 Month 30 mg

List Number: 2108; 2282; 2440; 3641; 3663; 3642; 3346; 3683

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Polymers of lactic and glycolic acid L-02-3639	<50	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Mannitol 69-65-8	<50	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Leuprolide Acetate 74381-53-6	3-7	Not Listed	Not Listed	Not Applicable	0.05 mcg/m ³	None
Carboxymethylcellulose Sodium 9004-32-4	3-5	15 mg/m ³ total dust; 5 mg/m ³ respirable dust	10 mg/m ³ total dust; 3 mg/m ³ respirable dust	Not Applicable	Not Applicable	None
Water 7732-18-5	<1	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Gelatin 9000-70-8	0-1	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Polysorbate 80 9005-65-6	<1	Not Listed	Not Listed	Not Applicable	Not Applicable	None

Notes: OSHA PEL: US Occupational Safety and Health Administration-Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.

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3. HAZARDS IDENTIFICATION

Emergency Overview:

Liquid.
Odor not determined.
The following hazards are associated with the active pharmaceutical ingredient in this product: Potent compound.
Developmental hazard. Reproductive hazard.

Routes of Exposure:

Oral: Unlikely
Dermal: Unlikely
Inhalation: Unlikely

Hazard Information:

Ingestion Rating: Not determined.
Skin Absorption Rating: Highly Toxic
Inhalation Rating: Not determined.
Corrosiveness Rating: Not determined.
Skin Contact Rating: Not determined.
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Not determined.
Target Organs: Reproductive System, Fetus, Endocrine system (hormones).

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Polymers of lactic and glycolic acid	<50	Not Listed	Not Listed	Not Listed	Not Listed
Mannitol	<50	Not Listed	Not Listed	Not Listed	Not Listed
Leuprolide Acetate	3-7	Not Listed	Not Listed	Not Listed	Not Listed
Carboxymethylcellulose Sodium	3-5	Not Listed	Not Listed	Not Listed	Not Listed
Water	<1	Not Listed	Not Listed	Not Listed	Not Listed
Gelatin	0-1	Not Listed	Not Listed	Not Listed	Not Listed
Polysorbate 80	<1	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating: Not determined.
Health: 3

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.

Notes to Physician: 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.

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

4. FIRST AID MEASURES

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4. 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.

5. FIRE FIGHTING MEASURES

Flammability:

Lower Explosive Limit: Not determined.

Autoignition Temp. (°C): Not determined.

Fire-Fighting Information:

Suitable Extinguishing Media: Use appropriate medium for the underlying cause of the fire.

Special Exposure Hazards: Avoid inhalation of combustion products.

6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.

Personal Precautions: Use personal protective equipment identified in Section 8.

Environmental Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: Not determined.

Storage: Store according to label instructions.

Special Precautions: Not applicable.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: None known.

Eyes: Wear eye protection appropriate to handling activities.

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Gloves: Impervious gloves.

Other PPE Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Liquid.
Odor: Odor not determined.
Boiling Pt. @ 760 mm Hg (°C): Not determined.
Melting/Freezing Point (°C): Not determined.
Vapor Pressure (mm Hg) Not determined.
Bulk Density at 20°C: Not determined.
Solubility: Not determined.
Specific Gravity: Not determined.
pH: Not determined.
Viscosity (centipoise): Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Not determined.

Self-Heating Tendency: Not determined.

Materials to Avoid: Not determined.

Hazardous Decomposition Products: Not determined.

Hazardous Polymerization: Not determined.

Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: No effect anticipated from intact clinical product.

Ingredients	Percent	Acute Test	Value	Units	Species
Mannitol	<50	LD50 =	13,500-22,000	mg/kg	Mice Rats
Leuprolide Acetate	3-7	LD50 >	5000	mg/kg	Mice Rats
Carboxymethylcellulose Sodium	3-5	LD50 =	19000 27000	mg/kg	Guinea Pigs Mice Rabbits
Polysorbate 80	<1	LD50 =	25,000 - 36,570	mg/kg	Mice Rats

Acute Toxicity - Dermal: Not determined. No effect anticipated from intact clinical product. Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Carboxymethylcellulose Sodium	3-5	LD50 >	2000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Not determined. No effect anticipated from intact clinical product. Data for component (s) given below.

Ingredients	Percent	Test	Value	Units	Species
Carboxymethylcellulose Sodium	3-5	LC 50 >	5800	mg/m ³	Rats

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Notes to Toxicologist: Intranasal application of leuprolide has produced pharmacologic responses in men and women at doses of 50 mcg or more.

Ingredients	Percent	Test Type	Value	Units	Species	Comments
Leuprolide Acetate	3-7	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.

Target Organ Effects: Not determined. None expected from normal clinical use of this product. Data for component (s) given below. Active Ingredient : In clinical use target organ effects include: male reproductive system, female reproductive system, fetus.

Ingredients	Percent	Target Organs:	Species	Dosage	Units	Route	Duration
Mannitol	<50	Eyes Kidney	Rats Mice	25,000	ppm	Oral Diet	Repeat dose study (ies).

Reproductive Effects: Not determined. None expected from normal clinical use of this product. Active Ingredient : In animal and human data, adverse reproductive effects included : male reproductive system, female reproductive system. Abbott SCHH : Potent Drug.

Ingredients	Percent	Reproductive Effects	Species	Dosage	Units	Route	Duration
Leuprolide Acetate	3-7	Female Reproductive System	Rats	24	mcg/mg	Subcutaneous	During Gestation Premating in Males
		Fetal Toxicity	Rats	72	mcg/mg		
		Male Reproductive System					

Leuprolide Acetate : In clinical use, subcutaneous doses of 1 mg/day act as potent, but reversible, inhibitors of GnRH secretion by the pituitary resulting in inhibition of ovarian and testicular function. In contrast, doses as low as 0.00036 mg or more stimulate gonadotropin release. In rabbits, subcutaneous dosages as low as 0.1 mcg/kg/day produced embryoletality withle doses of 10 mcg/kg/day produced fetal resorptions in rats. Materials similar to leuprolide have the potential to exert a contraceptive effect in pregnant women if administered 5-8 days after the LH surge.

Carcinogenicity: None expected from normal clinical use of this product. Active ingredient : In animals produced tumors in the following tissue (s): pituitary gland.

Ingredients	Percent	Site of Tumors	Species	Dosage	Units	Route	Duration
Leuprolide Acetate	3-7	Pituitary gland.	Rats	0.6 - 4	mg/kg/day	Not Specified	Unspecified

Leuprolide Acetate : Benign pituitary hyperplasia and tumors were found in carcinogenicity studies in rats (0.6-4 mg/kg/day). A study in mice at dosages up to 60 mg/kg/day was negative and no comparable effect has been found in man at doses up to 20 mg/day.

Mutagenicity: 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

12. ECOLOGICAL INFORMATION

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12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined.

Biodegradation: Not determined.

General Notes: 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.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

DOT/ADR:
Status: Not Regulated.

ICAO/IATA:
Status: Not Regulated.

IMDG:
Status: Not Regulated.

TDG (Canada):
Status: Not Regulated.

15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Polymers of lactic and glycolic acid	<50	No	Not Applicable	Not applicable
Mannitol	<50	No	Not Applicable	Not applicable
Leuprolide Acetate	3-7	No	Not Applicable	Not applicable
Carboxymethylcellulose Sodium	3-5	No	Not Applicable	Not applicable
Water	<1	No	Not Applicable	Not applicable
Gelatin	0-1	No	Not Applicable	Not applicable
Polysorbate 80	<1	No	Not Applicable	Not applicable

SARA 311/312 Hazard Categories:

Immediate Health: Not determined.

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Delayed Health: Not determined.
Fire: Not determined.
Sudden Pressure: Not determined.
Reactivity: Not determined.

TSCA Inventory Status: Not determined.

CERCLA Status: Not determined.

RCRA Status: Not determined.

Proposition 65 Status: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Ingredients	Percent	Proposition 65 Listed Materials
Leuprolide Acetate	3-7	developmental toxicity, initial date 8/26/97

EC HAZARD CLASSIFICATION:

Category of Danger: Exempt.
Indication of danger: None.
Risk Phrases: Exempt.
Risk Combination Phrases: None
Safety Phrases: Exempt.
Safety Combination Phrases: None

GHS CLASSIFICATION: Exempt

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.
Canadian NDSL: Not determined.
WHMIS Hazard Class: Exempt

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.

16. OTHER INFORMATION

Document Authored By: Global Occupational Toxicology (D-03QW)

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