



120 Centennial Ave
Piscataway
NJ 08854, USA

Material Safety Data Sheet

Technical phone	732-885-9188 ext 127
Emergency phone	732-885-9188 ext 111
Fax	732-210-0262
Email	info@genscript.com
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Section 1-Product Information

Product name	Leuprolide Acetate
Product Cat. No.	RP17321

Section 2-Composition / Information on Ingredients

Substance/Preparation:	Substance
Ingredient Name	Depo-Lupron, Leuplin, Leuprolide acetate, Leuprorelin acetate, Lupron, Lupron Depot, TAP-144, TAP-144-SR
CAS No.	74381-53-6
SARA 313	No
Formula	C ₅₉ H ₈₄ N ₁₆ O ₁₂ ·C ₂ H ₄ O ₂

Section 3- Hazards Identification

Emergency Overview	
Caution	The chemical, physical, and toxicological properties of this product have not been thoroughly investigated. Exercise due care.
HMIS Rating	
Health	1
Flammability	0
Reactivity	0
NFPA Rating	
Health	1
Flammability	0
Reactivity	0

For additional information on toxicity, please refer to Section 11.

Section 4- First Aid Measures

Oral Exposure	If swallowed, wash out mouth with water provided person is conscious. Call a physician.
Inhalation Exposure	If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.
Dermal Exposure	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.
Eye Exposure	In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

Section 5- Fire Fighting Measures

Flash Point	Not available
Autoignition Temp	Not available
Flammability	Not available
Extinguishing Media	
Suitable	Carbon dioxide, dry chemical powder, or appropriate foam. Water spray
Fire Fighting	
Protective Equipment	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Specific Hazard(s)	Emits toxic fumes under fire conditions.

Section 6- Accidental Release Measures

Procedure to be Followed in Case of Leak or Spill	Evacuate area
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Procedure(s) of Personal Precaution(s)	Wear respirator, chemical safety goggles, rubber boots, and heavy rubber gloves
Methods for Cleaning up	Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

Section 7-Handling and Storage

Handling	
User Exposure	Avoid inhalation. Avoid contact with eyes, skin, and clothing. Avoid prolonged or repeated exposure.
Storage	
Suitable	Keep tightly closed
Storage at -20°C	

Section 8-Exposure Controls/Personal Protection Equipment

Engineering Controls	Mechanical exhaust required
Personal Protective equipment	
Respiratory	Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks.
Hand	Protective gloves
Eye	Chemical safety goggles
General Hygiene Measures	Wash thoroughly after handling

Section 9- Physical and Chemical Properties

Appearance	
Physical State	White powder
Property	
Molecular Weight	1209.4 AMU
pH	Not available
BP/BP Range	Not available
MP/MP Range	Not available
Freezing Point	Not available
Vapor Pressure	Not available
Vapor Density	Not available
Saturated Vapor Conc.	Not available
SG/Density	Not available
Bulk Density	Not available
Odor Threshold	Not available
Volatile%	Not available
VOC Content	Not available
Water Content	Not available
Solvent Content	Not available
Evaporation Rate	Not available
Viscosity	Not available
Surface Tension	Not available
Partition Coefficient	Not available
Decomposition Temp.	Not available
Flash Point	Not available
Explosion Limits	Not available
Flammability	Not available
Autoignition Temp	Not available
Refractive Index	Not available
Optical Rotation	Not available
Miscellaneous Data	Not available
Solubility	Not available

Section 10- Stability and Reactivity

Stability	
Stable	Stable

Materials to Avoid	Strong oxidizing agents
Hazardous Decomposition Products	
Hazardous Decomposition Products	Carbon monoxide, Carbon dioxide, Nitrogen oxides
Hazardous Polymerization	
Hazardous Polymerization	Will not occur

Section 11- Toxicological Information

Route of Exposure	
Skin Contact	May cause skin irritation
Skin Absorption	May be harmful if absorbed through the skin
Eye Contact	May cause eye irritation.
Inhalation	Material may be irritating to mucous membranes and upper respiratory tract, May be harmful if inhaled.
Ingestion	May be harmful if swallowed
Signs And Symptoms of Exposure	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.
TOXICITY DATA	
Oral	Rat > 5000 mg/kg LD50
Intraperitoneal	Rat >5 mg/kg LD50
Subcutaneous	Rat >5 mg/kg LD50 Remarks: Skin and Appendages: Skin: After systemic exposure: Dermatitis, other
Intravenous	Rat 29900 ug/kg LD50
Intramuscular	Rat >2 mg/kg LD50 Remarks: Skin and Appendages: Skin: After systemic exposure: Dermatitis, other
Oral	Mouse > 5000 mg/kg LD50 Remarks: Gastrointestinal: Hypermotility, diarrhea.
Intraperitoneal	Mouse >5 mg/kg LD50 Remarks: Blood: Changes in spleen.
Subcutaneous	Mouse >5 mg/kg LD50 Remarks: Skin and Appendages: Skin: After systemic exposure: Dermatitis, other

Intravenous	Mouse 137 mg/kg LD50
Intramuscular	Mouse >2 mg/kg LD50 Remarks: Skin and Appendages: Skin: After systemic exposure: Dermatitis, other
Chronic Exposure - Teratogen	
Species	Rat
Dose	24 ug/mg
Route of Application	Subcutaneous
Exposure Time:	1D PREG
Result	Specific Developmental Abnormalities: Musculoskeletal system. Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Result: May cause reproductive disorders.
Chronic Exposure - Reproductive Hazard	
Species	Rat
Dose	72 ug/mg
Route of Application	Subcutaneous
Exposure Time	8W MALE
Result	Paternal Effects: Other effects on male. Paternal Effects: Testes, epididymis, sperm duct.
Species	Rat
Dose	24 ug/mg
Route of Application	Subcutaneous
Exposure Time	4W PRE
Result	Effects on Newborn: Sex ratio. Effects on Fertility: Pre-implantation mortality (e.g., reduction in number of implants per female; total number of implants per corpora lutea).
Species	Rat
Dose	1800 mg/kg
Route of Application	Subcutaneous
Exposure Time	90D MALE
Result	Paternal Effects: Prostate, seminal vessicle, Cowper's gland, accessory glands. Paternal Effects: Testes, epididymis, sperm duct.
Species	Rabbit
Dose	24 ug/mg
Route of Application	Subcutaneous
Exposure Time	6D PREG
Result	Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Effects on Fertility: Post-implantation mortality (e.g., dead and/or resorbed implants per total number of implants).

Section 12- Ecological Information

No data available.

Section 13- Disposal Considerations

Appropriate Method of Disposal of Substance or Preparation

Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations.

Section 14- Transport Information

DOT	Proper Shipping Name Non-Hazardous for Transport	None This substance is considered to be non-hazardous for transport.
IATA	Non-Hazardous for Air Transport	Non-hazardous for air transport

Section 15- Regulatory Information

EU Additional Classification	S	22-24/25
Safety Statements:		Do not breathe dust. Avoid contact with skin and eyes.
US Classification and Label Text	US Statements	Caution: Avoid contact and inhalation. Calif. Prop. 65 developmental hazard.
United States Regulatory information	SARA Listed	No
United States	California Prop - 65	State Regulatory Information
California Prop - 65	California Prop - 65	This product is or contains chemical(s) known to the state of California to cause developmental toxicity.
Canada Regulatory information	WHMIS Classification	This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR.
DSL		No
NDSL		No

Section 16- Other Information

GenScript corporation MSDS is believed to be correct but only used as a guide for experienced personnel, GenScript shall not be held liable for any damage resulting from the handling or from contact with the above product.