


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	LEUPROLIDE ACETATE, USP
PRODUCT CODE	2629
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 5) Toxic to Reproduction (Category 1A)	
PICTOGRAM		
SIGNAL WORD	Danger	
HAZARD STATEMENT(S)	May be harmful if swallowed. May damage fertility or the unborn child. Cytotoxic! Extremely hazardous to all tissues. May cause allergic reaction. CAUTION: Leuprolide Acetate is a potent hormonal manipulator avoid skin contact and inhalation of dusts and mists.	
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.	
PRECAUTIONARY STATEMENT(S)	Prevention	Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection.
	Response	IF SWALLOWED: Get medical help. IF EXPOSED OR CONCERNED: Get medical advice.
	Storage	Store locked up.
	Disposal	Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION	Health Hazard	4	Flammability	0
	Reactivity	0	Personal Protection	K

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Luteinizing hormone-releasing factor, 6-D-Leucine-9-(N-ethyl-L-prolinamide)-10-deglycinamide acetate (salt)
BOTANICAL NAME	Not applicable
SYNONYM	Leuprorelin Acetate
CHEMICAL FORMULA	C ₅₉ H ₈₄ N ₁₆ O ₁₂ (C ₂ H ₄ O ₂) _n ; n = 1 or 2
CHEMICAL FAMILY	Synthetic gonadotropin-releasing hormone analog
CAS NUMBER	74381-53-6
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	1269.5 (monoacetate)

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
LEUPROLIDE ACETATE	74381-53-6	686-285-8	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	If at any time there is skin contact with any cytotoxic drug, thoroughly wash the affected area with soap and water for 15 minutes. The worker should not scrape or abrade the skin by using a scrub brush as this could increase exposure. It is always recommended to seek a medical evaluation by a physician.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Refer to section 11.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
FLAMMABLE PROPERTIES	May be combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES
PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

The use of chemical inactivates is not recommended as they may create a hazardous by-product. All contaminated areas should be cleaned a minimum of three times, and all contaminated products and equipment should be disposed of or cleaned in an appropriate manner.

CLEANUP PROCEDURE

A clearly labelled cytotoxic spill kit should be kept wherever cytotoxic medications are being prepared, stored, administered or received (shipping). A spill needs to be cleaned by members of the staff that have received the appropriate training and have the appropriate protective equipment; others should vacate the area as soon as it is safe to do so until the spill is cleaned. All spills should be immediately marked with a warning sign to prevent exposure to others. Glass should never be handled by hand; always use a scoop. The cleanup should be done by as few people as feasible, but there should be at least two people involved.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE
PRECAUTIONS FOR SAFE HANDLING

Cytotoxic! Extremely hazardous to all tissues. Avoid all contact. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store at controlled room temperature. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: LEUPROLIDE ACETATE CAS #: 74381-53-6

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Cytotoxic: There are no exposure limits set for cytotoxic drugs. Exposure must be kept to a minimum.

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Chemical splash goggles, and if necessary, full-face protection. Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Protective gloves made of vinyl or nitrile rubber. Gloves should be changed frequently, or immediately if punctured, cut, or torn. It is also recommended that workers wear two pairs at a time for additional protection. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. A moisture resistant, long sleeved gown with elastic cuffs. To prevent the spread of medication, protective clothing should not be worn outside of the preparation area. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. In cases where there is a possibility of the medication becoming airborne, a powered air purifying respirator is recommended. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

The following engineering controls should be put in place where cytotoxic medications are being used: A minimum of a Class II biological safety cabinet with HEPA filter exhaust systems that does not allow air to be circulated back into the room should be used while manipulating cytotoxic drugs. The preparation area within the cabinet should be covered with a plastic backed, absorbent material to reduce dispersion and facilitate the clean-up of any spilled medication. Medications should be isolated and locked out in such a manner that only those properly trained have access to the storage location. Puncture proof containers for the disposal of needles, syringes and vials must be provided. Negative pressure rooms that prevent any spilled medication from leaving the room are also recommended.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

USP: ELV: Industrial: TWA: 0.05 micrograms/m³

Additional controls:

Safe work procedures for handling these materials should be developed and taught to all affected staff. Proper signage informing all employees of the presence of cytotoxic drugs and their hazards must be developed and displayed in highly visible locations. Eating, drinking, smoking, applying makeup and the storage of food should be completely prohibited in the preparation area.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

White or off white, hygroscopic powder.

SOLUBILITY

Soluble in water and acetic acid

ODOR

Slight odor or odorless.

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	Not available
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	5.3 - 6.3
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	Not available	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Hypochlorite solutions. Strong oxidizers.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures. Hygroscopic - Avoid exposure to moisture.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): > 5000 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Due to lack of data the classification is not possible.
GERM CELL MUTAGENICITY	Exposure to cytotoxic drugs has been reported to cause increased frequency of chromosome damage in exposed workers.
CARCINOGENICITY	OSHA LEUPROLIDE ACETATE is not listed. NTP LEUPROLIDE ACETATE is not listed. IARC LEUPROLIDE ACETATE is not evaluated. California Proposition 65 This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: LEUPROLIDE ACETATE.

ADDITIONAL CARCINOGENICITY INFORMATION

Repeated long-term occupational exposure to small amounts of cytotoxic drugs has not been identified to cause cancer. However, many cytotoxic drugs are known to be: Genotoxic, Carcinogenetic, Mutagenic.

REPRODUCTIVE TOXICITY

Adults treated with doses of a related material for at least two years have not shown evidence of carcinogenicity. Studies in animals administered a related material have given mixed results.

Cytotoxic drugs have also been associated with negative health effects for developing fetuses, including higher incidences of spontaneous abortions, congenital malformations, low birth weight, and infertility.

May damage fertility or the unborn child.

Related material: Therapeutic use can reversibly suppress male and female fertility, resulting in the absence of testosterone secretion or ovulation and/or menstruation. Miscarriage can also occur.

Adverse reproductive effects were seen in animal studies with a related material.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Infertility.

Symptoms related to the physical, chemical, and toxicological characteristics:

In males and females: Irregular heartbeat. Sweating. Flushing. Blurred vision. Decreased sexual desire.

Dizziness. Swelling of extremities. Headache. Nausea. Vomiting. Swelling or tenderness of breasts. Insomnia. Weight gain.

In males: Constipation. Decreased testicle size. Impotence.

In females: Change in menstrual cycle. Vaginal bleeding. Pelvic pain. Vaginal itching. Vaginal dryness.

Cross sensitivity:

Persons sensitive to gonadorelin (GnRH) or to gonadotropin-releasing hormone analogs (GnRHa) such as buserelin, goserelin, histrelin, and nafarelin may be sensitive to this material also.

Medical conditions aggravated by exposure:

Pregnancy. Metastatic vertebral lesions. Urinary tract obstruction. Mental depression

POTENTIAL HEALTH EFFECTS
Inhalation

Harmful if inhaled. May cause respiratory tract irritation. Leuprolide Acetate is a potent hormonal manipulator avoid inhalation of dusts and mists.

Ingestion

May be harmful if swallowed. Leuprorelin acetate is not active if given orally.

Skin

Harmful if absorbed through skin. May cause skin irritation. Leuprolide Acetate is a potent hormonal manipulator avoid skin contact.

Eyes

May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available

LC50: 96 Hr: Fish: (mg/L): Not available

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

Not available

MOBILITY IN SOIL

Soluble in water

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

Plastic bags that are at least 2mm thick (if polypropylene) or 4mm thick (if polyethylene) should be used to collect potentially contaminated materials. Bags should be color-coded and labeled with a cytotoxic warning label. All sharps should be placed in puncture proof containers before bagging. All workplaces should have a policy for segregating waste materials resulting from cytotoxic drug preparation and administration. These plans must meet or exceed the government regulations for hazardous waste disposal.

Housekeeping staff should wear protective gloves while handling waste containers. Cytotoxic waste must be handled differently than regular garbage and must be disposed according to government regulations. In cases where the waste is to be incinerated, it should be noted that completely sealed (airtight) containers that could build pressure and explode must be avoided. Temperatures of 1,000°C to 1,600°C should be used to render the cytotoxic drugs harmless.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA

HAZCHEM

Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not Listed

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
LEUPROLIDE ACETATE, 74381-53-6	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
LEUPROLIDE ACETATE, 74381-53-6	N/L	Listed as Schedule 4*	N/L	Listed*	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
LEUPROLIDE ACETATE, 74381-53-6	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

NOTES

*Listed as the base (Leuprorelin)

SECTION 16: OTHER INFORMATION
REFERENCES
ABBREVIATIONS AND ACRONYMS

Available upon request

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

04/2025

SUPERSEDES

03/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.

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