

# SAFETY DATA SHEET

Issue Date: 11/20/2024

Revision Date: New SDS

Revision Number: 01

## 1. IDENTIFICATION

**Product identifier:** Leuprolide Acetate Injection, USP

**Product Codes:** 0121-2106-02

**Supplier Name and Address:** Pharmaceutical Associates, Inc.  
201 Delaware Street

Greenville, SC 29605

**Telephone number:** (864) 277-7282

**Emergency phone number:** CHEMTREC 800-424-9300

**Recommended use:** Human drug – cancer treatment.

**Restrictions on use:** Use only as directed.

## 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Respiratory Sensitization Category 1 Skin Sensitization Category 1 Reproductive Toxicity Category 1A

**Label Elements:**



**Warning!**

**Hazard statement(s)**

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May damage fertility or the unborn child.

**Precautionary statement(s)**

Obtain special instructions before use.

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

Avoid breathing mists.

Contaminated clothing must not be allowed out of the workplace.

**Precautionary statement(s)**

In case of inadequate ventilation, wear respiratory protection.

Wear protective clothing and gloves.

IF INHALED: remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

IF on skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.

IF exposed or concerned: Get medical attention.

Store locked up.

Dispose in accordance with local and national regulations.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Leuprolide acetate	74381-53-6	0.5%
Water	7732-18-5	Proprietary

Sodium chloride	7647-14-5	Proprietary
Benzyl alcohol	100-51-6	<1%
Acetic Acid	64-19-7	<1%
Sodium hydroxide	1310-73-2	<1%

The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation occurs or other symptoms occur, get medical attention.

**Skin contact:** Wash skin with soap and water. If irritation or rash develops, get medical attention. Launder clothing before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** If swallowed, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

**Most important symptoms/effects, acute and delayed:** May cause mild eye irritation. Swallowing may cause gastrointestinal disturbances.

**Indication of immediate medical attention and special treatment, if necessary:** Medical attention is recommended for ingestion.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use any media that is suitable for the surrounding fire.

**Specific hazards arising from the chemical:** This product is not a fire hazard.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

#### 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure guidelines:

Leuprolide acetate	None Established
Water	None Established
Sodium chloride	None Established
Benzyl alcohol	10 ppm TWA AIHA&OARS WEEL
Acetic Acid	10 ppm TWA 15 ppm STEL ACGIH TLV 10 ppm TWA OSHA PEL
Sodium hydroxide	2 mg/m <sup>3</sup> Ceiling ACGIH TLV 2 mg/m <sup>3</sup> TWA OSHA PEL

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

### Individual protection measures:

**Respiratory protection:** None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** None required for normal use. Impervious gloves recommended for manufacturing operations.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.

**Other:** None known.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance (physical state, color, etc.):** Clear, colorless solution

**Odor:** Slight

<b>Physical State:</b> Liquid	<b>Color:</b> Colorless
<b>Odor:</b> Slight	<b>pH:</b> Not available
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not determined
<b>Flash point:</b> Not applicable	<b>Particle Characteristics:</b> Not applicable
<b>Flammability:</b> Not flammable	<b>VOC:</b> Not determined
<b>Flammable limits: LEL:</b> Not determined	<b>UEL:</b> Not determined
<b>Vapor pressure:</b> Not determined	<b>Relative Vapor density:</b> Not determined
<b>Relative density:</b> 1.01	<b>Solubility(ies):</b> Soluble
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available
<b>Decomposition temperature:</b> Not available	<b>Kinematic Viscosity:</b> Not determined

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** None known.

**Conditions to avoid:** None known.

**Incompatible materials:** Avoid oxidizing agents.

**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

### Acute effects of exposure:

**Inhalation:** Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract.

Inhalation may cause an allergic respiratory reaction.

**Ingestion:** Swallowing may gastrointestinal upset.

**Skin contact:** May cause mild irritation. May cause an allergic skin reaction.

**Eye contact:** May cause mild irritation with redness and tearing.

**Chronic Effects:** None known.

**Sensitization:** Leuprolide acetate is a skin and respiratory sensitizer.

**Germ Cell Mutagenicity:** Components are not classified as germ cell mutagens. Mutagenicity studies have been performed with leuprolide acetate using bacterial and mammalian systems. These studies provided no evidence of a mutagenic potential..

**Reproductive Toxicity:** When administered on day 6 of pregnancy at test dosages of 0.00024, 0.0024, and 0.024 mg/kg to rabbits, leuprolide acetate produced a dose-related increase in major fetal abnormalities. Similar studies in rats failed to demonstrate an increase in major fetal malformations throughout gestation. There was increased fetal mortality and decreased fetal weights with the two higher doses in rabbits and with the highest dose in rats. The effects on fetal mortality are expected consequences of the alterations in hormonal levels brought about by this drug.

**Carcinogenicity:** None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. Two-year carcinogenicity studies were conducted in rats and mice. In rats, a dose-related increase of benign pituitary hyperplasia and benign pituitary adenomas was noted at 24 months when the drug was administered subcutaneously at high daily doses (0.6 to 4 mg/kg). There was a significant but not dose-related increase of pancreatic islet-cell adenomas in females and of testicular interstitial cell adenomas in males (highest incidence in the low dose group). In mice no pituitary abnormalities were observed at a dose as high as 60 mg/kg for two years.

### Acute Toxicity Values:

Leuprolide acetate: Oral rat LD50 >5000 mg/kg

## 12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

**Ecotoxicity values:** No data available.

**Persistence and degradability:** No data available.

**Bioaccumulative potential:** No data available.

**Mobility in soil:** No data is available.

**Other adverse effects:** None known.

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

**14. TRANSPORT INFORMATION**

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

**15. REGULATORY INFORMATION**

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Refer to Section 2 for the OSHA Hazard Classification.

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**California Proposition 65:** This product contains leuprolide acetate which is listed as a developmental, male and female reproductive toxin.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

**16. OTHER INFORMATION**

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**SDS Revision History:** New SDS.

**Disclaimer:** The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.