

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 1 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 1. Identification

GHS product identifier : Leuprolide Acetate Injection, USP
Other means of identification : Leuprolide Acetate Injection, USP
Product type : Liquid.

Relevant identified uses of the substance or mixture and uses advised against

Product use : Pharmaceuticals. For intended use only.
 Observe technical data sheet/instructions for use.
 Specific Treatments: Palliative treatment of advanced prostatic cancer.

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.
 8700 W. Bryn Mawr, Suite 600S
 Chicago, IL 60631

Telephone: 224-443-4617
 www.meithealpharma.com

e-mail address of person responsible for this SDS : info@meithealpharma.com

Emergency telephone number (with hours of operation) : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : H360 TOXIC TO REPRODUCTION - Category 1B

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360 - May damage fertility or the unborn child.

Precautionary statements

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 2 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 2. Hazards identification

- Prevention** : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves, protective clothing and eye or face protection.
- Response** : P308 + P313 - IF exposed or concerned: Get medical advice or attention.
- Storage** : P405 - Store locked up.
- Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Hazards not otherwise classified** : None known.

Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture
- Other means of identification** : Leuprolide Acetate Injection, USP

Ingredient name	Other names	%	Identifiers
water	-	≥90	CAS: 7732-18-5
benzyl alcohol	-	<1	CAS: 100-51-6
sodium chloride	-	<1	CAS: 7647-14-5
leuprorelin	-	≤1	CAS: 53714-56-0
sodium hydroxide	-	≤0.3	CAS: 1310-73-2
acetic acid	-	≤0.3	CAS: 64-19-7
nitrogen	-	≤0.3	CAS: 7727-37-9

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

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

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 3 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 4. First aid measures

Ingestion : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No specific data.
Inhalation : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
Skin contact : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
Ingestion : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments : No specific treatment.
Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 4 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 5. Fire-fighting measures

- Extinguishing media**
- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
 - Unsuitable extinguishing media** : Do not use water jet.
- Specific hazards arising from the chemical** : In a fire or if heated, a pressure increase will occur and the container may burst.
- Hazardous thermal decomposition products** : No specific data.
- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

- Personal precautions, protective equipment and emergency procedures**
- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
 - For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
- Methods and materials for containment and cleaning up**
- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 5 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 6. Accidental release measures

- Large spill** : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Contain and collect spillage with non-combustible, absorbent material e. g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
water	None.
benzyl alcohol	OARS WEEL (United States, 4/2022) TWA 8 hours: 10 ppm.
sodium chloride	None.
leuprorelin	None.
sodium hydroxide	ACGIH TLV (United States, 7/2023) C: 2 mg/m ³ . NIOSH REL (United States, 10/2020) CEIL: 2 mg/m ³ . OSHA PEL (United States, 5/2018)

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 6 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 8. Exposure controls/personal protection

acetic acid	<p>TWA 8 hours: 2 mg/m³. CAL OSHA PEL (United States, 5/2018) C: 2 mg/m³. ACGIH TLV (United States, 7/2023) TWA 8 hours: 10 ppm. TWA 8 hours: 25 mg/m³. STEL 15 minutes: 15 ppm. STEL 15 minutes: 37 mg/m³. NIOSH REL (United States, 10/2020) TWA 10 hours: 10 ppm. TWA 10 hours: 25 mg/m³. STEL 15 minutes: 15 ppm. STEL 15 minutes: 37 mg/m³. OSHA PEL (United States, 5/2018) TWA 8 hours: 10 ppm. TWA 8 hours: 25 mg/m³. CAL OSHA PEL (United States, 5/2018) STEL 15 minutes: 37 mg/m³. STEL 15 minutes: 15 ppm. C: 40 ppm. TWA 8 hours: 25 mg/m³. TWA 8 hours: 10 ppm. ACGIH TLV (United States, 7/2023) Oxygen depletion [asphyxiant].</p>
nitrogen	

- Appropriate engineering controls** : If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
- Individual protection measures**
- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 7 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 8. Exposure controls/personal protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Liquid. [Clear.]
- Color** : Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 5.5 to 6.5
- Melting point** : Not available.
- Boiling point or initial boiling point and boiling range** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not available.

Vapor pressure

Ingredient name	Vapor Pressure at 20°C			Vapor pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
water	17.5	2.3		92.258	12.3	

- Relative vapor density** : Not available.
- Relative density** : 1.004 [Water = 1]

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 8 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 9. Physical and chemical properties

Density	: 1.004 g/cm ³				
Solubility(ies)	: <table border="1" style="display: inline-table; vertical-align: middle;"> <thead> <tr> <th style="color: blue;">Media</th> <th style="color: blue;">Result</th> </tr> </thead> <tbody> <tr> <td>water</td> <td>Easily soluble</td> </tr> </tbody> </table>	Media	Result	water	Easily soluble
Media	Result				
water	Easily soluble				
Miscible with water	: Yes.				
Partition coefficient: n-octanol/water	: Not applicable.				
Auto-ignition temperature	: Not available.				
Decomposition temperature	: Not available.				
SADT	: Not available.				
Viscosity	: Dynamic (room temperature): Not available. Kinematic (room temperature): Not available. Kinematic (40°C (104°F)): Not available.				
Flow time (ISO 2431)	: Not available.				
<u>Particle characteristics</u>					
Median particle size	: Not applicable.				
<u>Other information</u>					
Physical/chemical properties comments	: No additional information.				

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 9 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
benzyl alcohol	LC50 Inhalation Dusts and mists	Rat - Male, Female	>4178 mg/m ³	4 hours
	LD50 Dermal	Rabbit	2000 mg/kg	-
	LD50 Oral	Rat	1230 mg/kg	-
sodium chloride	LD50 Oral	Rat	3000 mg/kg	-
sodium hydroxide	LD50 Oral	Rat	325 mg/kg	-
acetic acid	LC50 Inhalation Vapor	Rat	11000 mg/m ³	4 hours
	LD50 Dermal	Rabbit	1060 mg/kg	-
	LD50 Oral	Rat	3310 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
benzyl alcohol	Skin - Moderate irritant	Rabbit	-	24 hours 100 mg	-
sodium chloride	Eyes - Moderate irritant	Rabbit	-	10 mg	-
	Eyes - Moderate irritant	Rabbit	-	24 hours 100 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
sodium hydroxide	Eyes - Mild irritant	Rabbit	-	400 ug	-
	Eyes - Severe irritant	Rabbit	-	1 %	-
	Eyes - Severe irritant	Rabbit	-	0.5 minutes 1 mg	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50 ug	-
	Skin - Severe irritant	Rabbit	-	24 hours 500 mg	-
acetic acid	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 50 mg	-
	Skin - Severe irritant	Rabbit	-	525 mg	-

Sensitization

Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 10 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 11. Toxicological information

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
benzyl alcohol	Category 3	-	Respiratory tract irritation
sodium hydroxide	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No specific data.
- Inhalation** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Skin contact** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Ingestion** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 11 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 11. Toxicological information

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : May damage fertility or the unborn child.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
benzyl alcohol	1230	2000	N/A	N/A	1.5
sodium chloride	3000	N/A	N/A	N/A	N/A
sodium hydroxide	325	N/A	N/A	N/A	N/A
acetic acid	3310	1060	N/A	11	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
benzyl alcohol sodium chloride	Acute LC50 10 ppm Fresh water	Fish - <i>Lepomis macrochirus</i>	96 hours
	Acute EC50 2430000 µg/l Fresh water	Algae - <i>Navicula seminulum</i>	96 hours
	Acute EC50 519.6 mg/l Fresh water	Crustaceans - <i>Cypris subglobosa</i>	48 hours
	Acute EC50 402.6 mg/l Fresh water	Daphnia - <i>Daphnia magna</i>	48 hours
	Acute IC50 6.87 g/L Fresh water	Aquatic plants - <i>Lemna minor</i>	96 hours
	Acute LC50 1000000 µg/l Fresh water	Fish - <i>Morone saxatilis</i> - Larvae	96 hours
	Chronic LC10 781 mg/l Fresh water	Crustaceans - <i>Hyalella azteca</i> - Juvenile (Fledgling, Hatchling, Weanling)	3 weeks
	Chronic NOEC 6 g/L Fresh water	Aquatic plants - <i>Lemna minor</i>	96 hours
sodium hydroxide	Chronic NOEC 0.314 g/L Fresh water	Daphnia - <i>Daphnia pulex</i>	21 days
	Chronic NOEC 100 mg/l Fresh water	Fish - <i>Gambusia holbrooki</i> - Adult	8 weeks
	Acute EC50 40.38 mg/l Fresh water	Crustaceans - <i>Ceriodaphnia dubia</i>	48 hours

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 12 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 12. Ecological information

acetic acid	Acute LC50 125 ppm Fresh water Acute EC50 73400 µg/l Fresh water Acute EC50 65000 µg/l Fresh water	- Neonate Fish - <i>Gambusia affinis</i> - Adult Algae - <i>Navicula seminulum</i> Daphnia - <i>Daphnia magna</i> - Neonate	96 hours 96 hours 48 hours
	Acute LC50 32 mg/l Marine water Acute LC50 75000 µg/l Fresh water	Crustaceans - <i>Artemia salina</i> Fish - <i>Lepomis macrochirus</i>	48 hours 96 hours

Conclusion/Summary : Not available.

Persistence and degradability

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
benzyl alcohol	-	-	Readily
acetic acid	-	-	Readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
water	-1.38	-	Low
benzyl alcohol	0.87	-	Low
acetic acid	-0.17	3.16	Low
nitrogen	0.67	-	Low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 13 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Additional information

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.
Clean Water Act (CWA) 311: sodium hydroxide; acetic acid

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 14 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 15. Regulatory information

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : TOXIC TO REPRODUCTION - Category 1B

Composition/information on ingredients

Name	%	Classification
benzyl alcohol	<1	FLAMMABLE LIQUIDS - Category 4 ACUTE TOXICITY (oral) - Category 4 ACUTE TOXICITY (dermal) - Category 4 ACUTE TOXICITY (inhalation) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
sodium chloride	<1	EYE IRRITATION - Category 2A
leuprorelin	≤1	TOXIC TO REPRODUCTION - Category 1B
sodium hydroxide	≤0.3	CORROSIVE TO METALS - Category 1 ACUTE TOXICITY (oral) - Category 4 SKIN CORROSION - Category 1A SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
acetic acid	≤0.3	HNOC - Corrosive to digestive tract [severe] FLAMMABLE LIQUIDS - Category 3 ACUTE TOXICITY (dermal) - Category 4 ACUTE TOXICITY (inhalation) - Category 4 SKIN CORROSION - Category 1A SERIOUS EYE DAMAGE - Category 1 HNOC - Corrosive to digestive tract [severe]
nitrogen	≤0.3	HNOC - Corrosive to respiratory tract [severe] GASES UNDER PRESSURE - Compressed gas SIMPLE ASPHYXIANTS

SARA 313

Not applicable.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 15 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 15. Regulatory information

[Chemical Weapon Convention List Schedules I, II & III Chemicals](#)

Not listed.

[Montreal Protocol](#)

Not listed.

[Stockholm Convention on Persistent Organic Pollutants](#)

Not listed.

[Rotterdam Convention on Prior Informed Consent \(PIC\)](#)

Not listed.

[UNECE Aarhus Protocol on POPs and Heavy Metals](#)

Not listed.

Section 16. Other information

[Hazardous Material Information System \(U.S.A.\)](#)

Health	*	0
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

[National Fire Protection Association \(U.S.A.\)](#)



[Procedure used to derive the classification](#)

Classification	Justification
TOXIC TO REPRODUCTION - Category 1B	Calculation method

[History](#)

- Date of issue/Date of revision** : 04/08/2024
- Date of previous issue** : No previous validation
- Version** : 1.0

SDS Title: Leuprolide Acetate Injection, USP Safety Data Sheet	SDS Number: SDS-000084	Page Number: Page 16 of 16
Function: Regulatory Affairs	Effective Date: April 08, 2024	Version number: 1.0

Section 16. Other information

- Prepared by** : Sphera Solutions
- Key to abbreviations** :
- ATE = Acute Toxicity Estimate
 - AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift
 - BCF = Bioconcentration Factor
 - GHS = Globally Harmonized System of Classification and Labelling of Chemicals
 - IATA = International Air Transport Association
 - IBC = Intermediate Bulk Container
 - IMDG = International Maritime Dangerous Goods
 - LogPow = logarithm of the octanol/water partition coefficient
 - MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
 - N/A = Not available
 - UN = United Nations
- References** : HCS (U.S.A.)- Hazard Communication Standard
International transport regulations

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.