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|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 1 of 13 |

Section 1 - Identification


- (a) **Product Identifier:** Leuprolide Acetate Injection
- (b) **Product Code:** 83634-454
- Common/Trade Name:** Lupron, Leuprolide
- Chemical Name:** 5-oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-D-leucyl-L-leucyl- L-arginyl-N-ethyl-L-prolinamide acetate (salt)
- Chemical Family:** Hormone
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229


Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Sensitization, respiratory, Category 1
Reproductive toxicity, Category 1A
Sensitization, skin, Category 1

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| (b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s): | (c) Description of Hazards: |
| GHS Signal Word: | Danger |

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|----------------|--|-------------------------------------|---------------------------|------------------------|
| AVENACY | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 2 of 13 |

| | |
|--------------------------------------|--|
| GHS Hazard Statement: | <p>H317 - May cause an allergic skin reaction.</p> <p>H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p> <p>H360 - May damage fertility or the unborn child.</p> <p>P201 - Obtain special instructions before use.</p> <p>P202 - Do not handle until all safety precautions have been read and understood.</p> <p>P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.</p> <p>P272 - Contaminated work clothing must not be allowed out of the workplace.</p> <p>P280 - Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>P284 - [In case of inadequate ventilation] wear respiratory protection.</p> <p>P302+P352 - If on skin: Wash with plenty of water.</p> <p>P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.</p> <p>P308+P313 - If exposed or concerned: Get medical advice/attention.</p> <p>P321 - Specific treatment (see supplemental first aid instruction on this label).</p> <p>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.</p> <p>P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.</p> <p>P363 - Wash contaminated clothing before reuse.</p> <p>P405 - Store locked up.</p> <p>P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.</p> |
| GHS Symbols: |  |
| GHS Precautionary Statements: | Not available. |
| Other Hazards | An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8). |


| | | | | |
|---|--|-------------------------------------|---------------------------|------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 3 of 13 |

Section 3 – Composition / Information on Ingredients

| (a) Chemical Name | (b) Common Name / Synonym | % Composition or other measure | (c) CAS No. | (d) Impurities / Stabilizing Additives |
|--|------------------------------|---|-------------|---|
| 5-oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-D-leucyl-L-leucyl- L-arginyl-N-ethyl-L-prolinamide acetate (salt) | Leuprolide Acetate | 0.5% | 74381-53-6 | N/A |
| Water | Water | 99.5% | 7732-18-5 | NA |
| Sodium Chloride | Sodium Chloride | <1% | 7647-14-5 | NA |
| Benzyl alcohol | Benzyl alcohol | <1% | 100-51-6 | NA |
| Acetic Acid | Acetic Acid | <1% | 64-19-7 | NA |
| Sodium Hydroxide | Sodium Hydroxide | <1% | 1310-73-2 | NA |

Section 4 – First Aid Measures

- Eye Exposure:** 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 20 minutes. Get medical attention if irritation occurs.
- Skin Exposure:** Flush contaminated skin with plenty of water. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- 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.

| | | | | |
|---|--|-------------------------------------|---------------------------|------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 4 of 13 |

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.

Injection: See patient package insert in shipping carton for complete information.

Notes to Physician: See patient package insert in shipping carton for complete information.

Most important symptoms and effects, both acute and delayed:

Eye contact: Not applicable

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 any immediate medical attention and special treatment needed:

Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

Section 5 – Fire-fighting Measures

- | | |
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| (a) Extinguishing Media: | Suitable extinguishing media: Use an extinguishing agent suitable for the surrounding fire. Unsuitable extinguishing media: Do not use water jet. |
| (b) Hazardous Combustion Products: | In a fire or if heated, a pressure increase will occur and the container may burst. Specific hazards: May be combustible at high temperatures. |
| (c) Special Protective Equipment / Precautions: | During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus and turnout gear. |

Section 6 - Accidental Release Measures

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|---|--|-------------------------------------|---------------------------|------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 5 of 13 |

**Health and Safety
Precautions:**

Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition. No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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".

**Measures for
Cleaning /
Collecting:**


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.
General cleaning method: Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

**Measures for
Environmental
Protections:**

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). Prevent further leakage or spillage if safe to do so.

**Additional
Considerations for
Large Spills:**

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. 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 (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product.

| | | | | |
|---|--|-------------------------------------|---------------------------|------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 6 of 13 |

Section 7 - Handling and Storage


General Handling: 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. 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. See also Section 8 for additional information on hygiene measures.

Storage Conditions: 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

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

| Compound | Issuer | Type | Exposure Limit |
|--------------------|----------|---------------|----------------------|
| Sodium Hydroxide | ACGIH | OEL | 2 mg/m ³ |
| | OSHA | PEL (TWA) | 2 mg/m ³ |
| | IDLH | | 10 mg/m ³ |
| | NIOSH | REL (Ceiling) | 2 mg/m ³ |
| Water | NA | NA | NA |
| Benzyl alcohol | AIHA | WEEL TWA | 10 ppm |
| Leuprolide Acetate | NA | NA | NA |
| Sodium Chloride | NA | NA | NA |
| Acetic Acid | ACGIH | OEL TWA | 10 ppm |
| | ACGIH | OEL STEL | 15 ppm |
| | OSHA | PEL (TWA) | 25 mg/m ³ |
| | OSHA | PEL (TWA) | 10 ppm |
| | IDLH | [ppm] | 50 ppm |
| | NIOSH | REL (TWA) | 25 mg/m ³ |
| | NIOSH | REL TWA | 10 ppm |
| | NIOSH | REL (STEL) | 37 mg/m ³ |
| NIOSH | REL STEL | 15 ppm | |

| | | | | |
|---|--|-------------------------------------|---------------------------|------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 7 of 13 |

(b) 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 process equipment will be necessary to reduce emissions to acceptable levels.

(c) Individual Protection Measures

| | |
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| Personal Protective Equipment: | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. |
| Eye Protection: | Safety glasses with side-shields or goggles. |
| Skin and Body Protection: | Long sleeved clothing, chemical resistant apron and gloves. |
| Respiratory Protection: | Effective dust mask or wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent. |
| Hygiene Measures: | Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke. |

Section 9 - Physical and Chemical Properties

| | | |
|------------|----------------------------------|-------------------|
| (a) | Appearance | Liquid, colorless |
| (b) | Odor | None |
| (c) | Odor Threshold | Not available |
| (d) | pH | Not available |
| (e) | Melting Point: | Not determined |
| (f) | Initial Boiling Point: | Not determined |
| (g) | Flash Point (Liquid) (°C) | Not determined |

| | | | | |
|---|--|-------------------------------------|---------------------------|------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 8 of 13 |


| | | |
|------------|---|----------------|
| (h) | Evaporation Rate: | Not determined |
| (i) | Flammability | Not determined |
| (j) | Upper Lower Flammability or Explosion Limits | Not determined |
| (k) | Vapor Pressure (kPa): | Not determined |
| (l) | Vapor Density: | Not determined |
| (m) | Relative Density | Not determined |
| (n) | Solubility(ies) | Not determined |
| (o) | Partition Coefficient: n-octanol/water | Not available |
| (p) | Auto-ignition Temperature | Not available |
| (q) | Decomposition Temperature | Not available |
| (r) | Viscosity | Not available |

Section 10 - Stability and Reactivity

| | | |
|------------|---|--|
| (a) | Reactivity | Not determined |
| (b) | Chemical Stability | Stable under standard use and storage conditions. |
| (c) | Possibility of Hazardous Reactions | Under normal conditions of storage and use, hazardous reactions will not occur. |
| (d) | Conditions to Avoid | No data available. |
| (e) | Incompatible Materials | Reactive or incompatible with the following materials: oxidizing materials. |
| (f) | Hazardous Decomposition Products | Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

Section 11 - Toxicological Information


| | | |
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| (a) | Likely Routes of Exposure | Skin, eyes, ingestion, inhalation |
| (b) | Symptoms related to the physical, chemical and toxicological characteristics | Reduced fetal weight Increase in fetal deaths Skeletal malformations |

| | | | | |
|---|--|-------------------------------------|---------------------------|------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 9 of 13 |

| | | |
|------------|--|--|
| (c) | Delayed and immediate effects and chronic effects from short and long term exposure | <p>General: No known significant effects or critical hazards.</p> <p>Carcinogenicity: No known significant effects or critical hazards.</p> <p>Mutagenicity: No known significant effects or critical hazards.</p> <p>Teratogenicity: Suspected of damaging the unborn child.</p> <p>Developmental effects: No known significant effects or critical hazards.</p> <p>Fertility effects: Suspected of damaging fertility.</p> |
|------------|--|--|

(d) Acute Toxicity:

| Component | Type | Route | Species | Dosage |
|--------------------|--------------------------|---------------------------|---------|------------------------|
| Water | LD ₅₀ | Oral | Rat | >90 mL/kg |
| Sodium Chloride | LD ₅₀ /1 hr | Sub-tenon injection (eye) | Rat | >42 g/m ³ |
| Sodium Chloride | LD ₅₀ | Oral | Rat | 3 g/kg |
| Sodium Chloride | LD ₅₀ | Oral | Mouse | 4 g/kg |
| Sodium Chloride | LD ₅₀ | Dermal | Rabbit | >10 g/kg |
| Benzyl Alcohol | LD ₅₀ | Oral | Rat | 1230 mg/kg |
| Benzyl Alcohol | Acute Toxicity Estimates | ATE (Vapors) | - | 8.8 mg/L/4h |
| Benzyl Alcohol | Acute Toxicity Estimates | ATE (Derma) | - | 2000 mg/kg body weight |
| Acetic Acid | LD ₅₀ | Oral | Rat | 3310 mg/kg |
| Acetic Acid | LD ₅₀ | Inhalation | Rat | 16000 mg/kg/4hr |
| Sodium Hydroxide | LD ₅₀ | Oral | Rat | 140 to 340 mg/kg |
| Sodium Hydroxide | LD ₅₀ | Dermal | Rabbit | 1350 mg/kg |
| Sodium Hydroxide | Acute Toxicity Estimates | ATE (Dermal) | - | 1350 mg/kg body weight |
| Leuprolide Acetate | Acute Toxicity Estimates | ATE US (Gases) | - | 4500 ppmV/4h |
| Leuprolide Acetate | Acute Toxicity Estimates | ATE US (Vapors) | - | 11 mg/L/4h |
| Leuprolide Acetate | Acute Toxicity Estimates | ATE US (Dust, Mist) | - | 1.5 mg/L/4h |

| | | | | |
|---|--|-------------------------------------|---------------------------|-------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 10 of 13 |

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.


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| (a) Ecotoxicity | <p>Sodium chloride: Weight-%:0.1-1% Fish LC₅₀ 1259 mg/l (Exposure time: 96 h - Species: Fathead Minnow) Crustacea EC₅₀ 1661 mg/l (Exposure time: 48 h - Species: Daphnia magna)</p> <p>Benzy Alcohol: Weight-%:0.1-1% Crustacea EC₅₀ 23 mg/l (Exposure time: 48 h - Species: water flea)</p> <p>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.</p> |
| (b) Persistence and degradability | N/A |
| (c) Bioaccumulative potential | N/A |
| (d) Mobility in soil | N/A |
| (e) Other Adverse Effects | Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system. |

Section 13 - Disposal Considerations

Waste Disposal: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

Section 14 - Transport Information

- DOT: Not regulated as a dangerous good.
- IATA: Not regulated as a dangerous good.
- IMDG: Not regulated as a dangerous good.
- UN Number: Not regulated
- UN Proper Shipping Name: Not regulated
- Transport Hazard Class(es): Not regulated
- Packing Group: Not regulated

| | | | | |
|---|--|-------------------------------------|---------------------------|-------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 11 of 13 |

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

US Federal regulations:

Sodium hydroxide: Listed on the United States TSCA (Toxic Substances Control Act) inventory
CERCLA RQ : 1000 lb

Water: Listed on the United States TSCA (Toxic Substances Control Act) inventory

Benzyl alcohol: Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium chloride: Listed on the United States TSCA (Toxic Substances Control Act) inventory

Acetic acid: Listed on the United States TSCA (Toxic Substances Control Act) inventory
CERCLA RQ : 5000 lb

US State regulations:

Sodium hydroxide:

- U.S. - Massachusetts- Right To Know List
- U.S. - Minnesota- Hazardous Substance List
- U.S. - New Jersey - - Right to Know Hazardous Substance List
- U.S. - Pennsylvania- - RTK (Right to Know) List

Benzyl alcohol:

- U.S. - Massachusetts- Right To Know List
- U.S. - Minnesota- Hazardous Substance List
- U.S. - Pennsylvania- - RTK (Right to Know) List

Acetic acid:


- U.S. - Massachusetts- Right To Know List
- U.S. - Minnesota- Hazardous Substance List
- U.S. - New Jersey - - Right to Know Hazardous Substance List
- U.S. - Pennsylvania- RTK (Right to Know) List

Sodium chloride: Not applicable

Water: Not applicable

Section 16 - Other Information

As of the date of effectiveness, we are providing available information relevant to the handling

| | | | | |
|---|--|-------------------------------------|---------------------------|-------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 12 of 13 |


of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Avenacy
10 N. Martingale Road, Suite 225
Schaumburg, IL 60173
847-773-4901

Glossary: This glossary contains definitions of general terms used in SDSes. Not all of these Glossary Terms will apply to this SDS.

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| ACGIH | American Conference of Governmental Industrial Hygienists |
| AICS | Australian Inventory of Chemical Substances |
| AIHA | American Industrial Hygiene Association |
| ANSI | American National Standards Institute |
| CAS Number | Chemical Abstract Service Registry Number |
| CERCLA | Comprehensive Environmental Response Compensation and Liability Act (of |
| CHAN | Chemical Hazard Alert Notice |
| CHEMTREC | Chemical Transportation Emergency Center |
| DOT | Department of Transportation |
| DSL | Domestic Substances List |
| ECHA | European Chemicals Agency |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| EPA | Environmental Protection Agency |
| GHS | Globally Harmonized System of Classification and Labelling of Chemicals |
| HEPA | High Efficiency Particulate Air (Filter) |
| HMIS | Hazardous Materials Identification System |
| IARC | International Agency for Research on Cancer |
| ICAO/IATA | International Civil Aviation Organization/International Air Transport |
| IMO | International Maritime Organization |
| KOW | Octanol/Water Partition Coefficient |
| LEL | Lower Explosive Limit |
| MSDS | Material Safety Data Sheet |
| MSHA | Mine Safety and Health Administration |
| NA | Not Applicable, except in Section 14 where NA = North America |
| NE | Not Established |
| NADA | New Animal Drug Application |
| NAIF | No Applicable Information Found |
| NCI | National Cancer Institute |
| NDSL | Non-Domestic Substances List |
| NFPA | National Fire Protection Association |
| NIOSH | National Institute for Occupational Safety and Health |
| NPDES | National Pollutant Discharge Elimination System |

| | | | | |
|---|--|-------------------------------------|---------------------------|-------------------------|
|  | Document Type: Safety Data Sheet | Leuprolide Acetate Injection | | |
| | Effective Date: 13 FEB 2025 | SDS No.: SDS026 | Revision No: 01 | Page 13 of 13 |

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|-------|--|
| NOS | Not Otherwise Specified |
| NTP | National Toxicology Program |
| OSHA | Occupational Safety and Health Administration |
| OEL | Occupational Exposure Limit |
| PEL | Permissible Exposure Limit (OSHA) |
| RCRA | Resource Conservation and Recovery Act |
| RQ | Reportable Quantity |
| RTECS | Registry of Toxic Effects of Chemical Substances |
| SARA | Superfund Amendments and Reauthorization Act |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value (ACGIH) |
| TPQ | Threshold Planning Quantity |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UEL | Upper Explosive Limit |
| UN | United Nations |
| USP | United States Pharmacopeia |
| WEEL | Workplace Environmental Exposure Level (AIHA) |
| WHMIS | Workplace Hazardous Materials Information System |