SAFETY DATA SHEET

1. Identification
Product identifier Triptorelin Acetate

Other means of identification
Catalog number 1696131
CAS number 140194-24-7
Synonyms (D-Trp^6)-LHRH-acetate salt
Chemical name 5-Oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-D-tryptophyl-L-leucyl-L-arginyl-L-prolylglycinamide acetate salt

Recommended use Specified quality tests and assay use only.
Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information
Manufacturer
Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway
Rockville
MD 20852-1790
United States
Telephone RS Technical Services 301-816-8129
Website www.usp.org
E-mail RSTECH@usp.org
Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification
Physical hazards Not classified.
Health hazards Reproductive toxicity Category 1
Environmental hazards Not classified.
OSHA defined hazards Not classified.

Label elements

Signal word Danger
Hazard statement May damage fertility or the unborn child.
Precautionary statement
Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
Response If exposed or concerned: Get medical advice/attention.
Storage Store locked up.
Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)
None known.

Supplemental information Potent pharmacologically active material.

3. Composition/information on ingredients
Substance
Material name: Triptorelin Acetate
1696131 Version #: 02 Revision date: 02-14-2019 Issue date: 02-14-2019
4. First-aid measures

**Inhalation**
Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact**
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact**
Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms/effects, acute and delayed**
Reproductive system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically.

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**
Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire fighting equipment/instructions**
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**
No unusual fire or explosion hazards noted.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up**
For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

**Precautions for safe handling**
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

**Occupational exposure limits**
No exposure limits noted for ingredient(s).

**Biological limit values**
No biological exposure limits noted for the ingredient(s).
No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection**
Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

**Hand protection**
Train employees in proper gowing and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection**
Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards**
Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**
Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

### 9. Physical and chemical properties

**Appearance**
Appearance descriptions are general information and not specific to any USP lot.

**Physical state**
Solid.

**Form**
Powder.

**Color**
White.

**Odor**
Practically odorless.

**Odor threshold**
Not available.

**pH**
Not available.

**Melting point/freezing point**
Not available.

**Initial boiling point and boiling range**
Not available.

**Flash point**
Not available.

**Evaporation rate**
Not available.

**Flammability (solid, gas)**
Not available.

**Upper/lower flammability or explosive limits**

- **Flammability limit - lower (%)**
  Not available.

- **Flammability limit - upper (%)**
  Not available.

- **Explosive limit - lower (%)**
  Not available.

- **Explosive limit - upper (%)**
  Not available.

**Vapor pressure**
Not available.

**Vapor density**
Not available.

**Relative density**
Not available.

**Solubility(ies)**

- **Solubility (water)**
  Soluble.

- **Solubility (other)**
  Acetic acid: Freely soluble.
  Dimethyl formamide: Freely soluble.
  Hydrochloric acid: Freely soluble.
  Sodium Hydroxide: Freely soluble.

**Auto-ignition temperature**
Not available.
Decomposition temperature  
Not available.

Viscosity  
Not available.

Other information
  Chemical family  
Decapeptide.
  Molecular formula  
C64H82N18O13 . C2H4O2
  Molecular weight  
1371.53

10. Stability and reactivity

Reactivity
The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability
Material is stable under normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
Contact with incompatible materials.

Incompatible materials
None known.

Hazardous decomposition products
Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological information

Information on likely routes of exposure
Inhalation
May damage fertility or the unborn child by inhalation.

Skin contact
Knowledge about health hazard is incomplete.

Eye contact
Knowledge about health hazard is incomplete.

Ingestion
Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical, and toxicological characteristics
Decreased libido.

Information on toxicological effects

Acute toxicity
Not known.

Skin corrosion/irritation
Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation
Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization
Knowledge about health hazard is incomplete.

Skin sensitization
Knowledge about health hazard is incomplete.

Germ cell mutagenicity
Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test (Salmonella typhimurium)
Result: Negative.

In vivo (Mouse) micronucleus test
Result: Negative.

Mutagenicity: In mouse lymphoma L5178Y cells
Result: Negative.

Mutagenicity: In ovary cells
Result: Negative.

Species: Hamster, Chinese

Carcinogenicity
Knowledge about carcinogenicity is incomplete.

107 microgram/kg Carcinogenicity, administered intramuscularly monthly as microparticles.
Result: Dose-related pituitary adenomas.
Species: Rat

214 microgram/kg Carcinogenicity, administered intramuscularly monthly as microparticles.
Result: No carcinogenic effects.
Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.
Reproductive toxicity

May damage fertility or the unborn child.

Reproductivity

0.4 - 10 microgram/kg Reproductivity and development studies, triptorelin administered subcutaneously during organogenesis
Result: No maternal toxicity or teratogenicity. Increase in luteal bodies.
Species: Rat

0.5 - 50 microgram/kg Reproductivity and development studies, triptorelin administered subcutaneously during organogenesis
Result: Pre-implantation loss and increased incidence of resorption and abortions at high dose.
Species: Rabbit

375 microgram/kg Reproductivity and development studies, triptorelin administered as a single intramuscular injections twice during gestation.
Result: No maternal or embryotoxic effects.
Species: Monkey

4 - 400 microgram/kg Fertility study, administered subcutaneously.
Result: Males: decreased testosterone, atrophy of reproductive organs, loss or spermatogenesis. Females: decrease in progesterone, cessation of estrus cycle, ovarian atrophy, vaginal atrophy.
Species: Rat

Specific target organ toxicity - single exposure
Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure
Knowledge about health hazard is incomplete.

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

Further information
Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Since emptied containers may retain product residue, follow label warnings even after container is emptied.
14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

General information
It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
Classified hazard categories
Reproductive toxicity

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

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<th>Country(s) or region</th>
<th>Inventory name</th>
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<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
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<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
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<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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16. Other information, including date of preparation or last revision

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