SAFETY DATA SHEET

1. Identification

Product identifier: Goserelin System Suitability Mixture

Other means of identification

Catalog number: 1297250

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

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

Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goserelin Acetate</td>
<td></td>
<td>145781-92-6</td>
<td>93</td>
</tr>
<tr>
<td>Decarbamoylgoserelin acetate</td>
<td></td>
<td>No Data</td>
<td>4.66</td>
</tr>
</tbody>
</table>
4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact
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
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. For waste disposal, see section 13 of the SDS.

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

Exposure limit values

<table>
<thead>
<tr>
<th>Industrial Use Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goserelin Acetate (CAS 145781-92-6)</td>
<td>TWA</td>
<td>2.5 micrograms/m3</td>
</tr>
</tbody>
</table>

Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
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
Hand 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.

Other
Train employees in proper gowning 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
Crystalline. Lyophilized cake.

Color
White.

Odor
Not available.

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): Not available.
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.
Other information:
Chemical family: Synthetic gonadotropin-releasing hormone analog.

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: Strong oxidizing agents.
Hazardous decomposition products: Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure:
- Inhalation: Knowledge about health hazard is incomplete.
- 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:

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 sensitization hazard is incomplete.
- Germ cell mutagenicity: Knowledge about mutagenicity is incomplete. Negative in bacterial and mammalian assays for point mutations and cytogenic effects.
- Carcinogenicity:
  - Goserelin Acetate: 0.05 - 0.15 mg/kg/day Carcinogenicity, administered as subcutaneous implants. Result: Increased incidence of pituitary adenomas. Species: Rat Test Duration: 1 yr
  - 2.4 mg/kg/day Carcinogenicity, administered as subcutaneous implants. Result: Increased incidence of histiocytic sarcomas. Species: Mouse Test Duration: 2 yr

IARC Monographs. Overall Evaluation of Carcinogenicity: Not listed.
US. National Toxiconology Program (NTP) Report on Carcinogens: Not listed.
May damage fertility or the unborn child.

0.002 - 0.05 mg/kg/day Reproductivity study
Result: Dose-related increase in pregnancy losses.
Species: Rat

0.02 - 1 mg/kg/day Reproductivity study
Result: Dose-related increase in pregnancy losses.
Species: Rabbit

0.05 - 1 mg/kg/day Fertility study: Females.
Result: Decrease in size and weight of reproductive organs and suppression of ovarian function.
Species: Rat

0.5 - 1 mg/kg/day Fertility study: Males.
Result: Decrease in size of reproductive organs and suppression of spermatogenesis.
Species: Rat

> 10 mg/kg/day Reproductivity and development study
Result: Increased incidence of umbilical hernias.
Species: Rat

Knowledge about health hazard is incomplete.

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

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

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.

No data is available on the degradability of any ingredients in the mixture.

No data available.

No data available.

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

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.

Dispose in accordance with all applicable regulations.

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

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).

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

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.

  Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

- **SARA 302 Extremely hazardous substance**
  Not listed.

- **SARA 311/312 Hazardous chemical**
  Yes

  **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 Proposition 65**
  WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.
  For more information go to www.P65Warnings.ca.gov.

**International Inventories**

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and New Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

* "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
  * "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

**Issue date**
02-06-2019

**Revision date**
02-08-2019
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