SAFETY DATA SHEET

1. Identification

Product identifier: Gonadorelin Hydrochloride

Other means of identification:
- Catalog number: 1296803
- CAS number: 51952-41-1
- Synonyms: Luteinizing hormone-releasing factor hydrochloride

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
- Telephone: 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: Specific target organ toxicity, repeated exposure. Category 1 (endocrine system)

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements:

Signal word: Danger

Hazard statement: Causes damage to organs (endocrine system) through prolonged or repeated exposure.

Precautionary statement:
- Prevention: Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling.
- Response: Get medical advice/attention if you feel unwell.
- Storage: Not available.
- 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

Material name: Gonadorelin Hydrochloride

1296803 Version #: 03 Revision date: 03-07-2019 Issue date: 01-19-2011
### Chemical name and synonyms

**Common name and synonyms:**

- **Gonadorelin Hydrochloride:**
  - CAS number: 51952-41-1
  - **5-Oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosylglycyl-leucyl-L-arginyl-L-prolylglycinamide hydrochloride**

### 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

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

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. Wear appropriate protective equipment and clothing during clean-up. 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).
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 gowns 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 outerwear 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. Off-white.

Odor
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: 1%; Soluble.
Methanol: Sparingly soluble.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.
Other information

Chemical family: Synthetic polypeptide hormone.
Molecular formula: C55H75N17O13 . 2HCl
Molecular weight: 1255.44

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.
Hazardous decomposition products: NOx. Cl-. 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.

Information on toxicological effects

Acute toxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonadorelin Hydrochloride (CAS 51952-41-1)</td>
<td>Rat</td>
<td>&gt; 3000 mg/kg</td>
</tr>
</tbody>
</table>

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.
Carcinogenicity: Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.

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

US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity

Knowledge about health hazard is incomplete.
Miscarriage and multifetal pregnancies have been observed after ovulation induction treatment.

Reproductivity

0.1 mg/kg Reproductivity study
Result: No adverse effects on the offspring after subcutaneous doses during gestation.
Species: Rabbit
Reproductivity
2 mg/kg/day Reproductivity study
Result: No adverse effects on the fetus after intraperitoneal doses.
Species: Rat
4 mg/kg/day Reproductivity study
Result: No adverse effects on the fetus after intraperitoneal doses.
Species: Mouse

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

Specific target organ toxicity - repeated exposure
Causes damage to organs (endocrine system) through prolonged or repeated exposure.

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
Empty containers should be taken to an approved waste handling site for recycling or disposal. 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
Yes

Classified hazard categories
Specific target organ toxicity (single or repeated exposure)

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
This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

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>
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</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<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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<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
A "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: 01-19-2011
Revision date: 03-07-2019
Version #: 03

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