1. Identification

Product identifier: Insulin Glargine for Peak Identification

Other means of identification

Catalog number: 1342060

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

Company name: U. S. Pharmacopeia
Address: 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

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: Not classified.

OSHA hazard(s): Not classified.

Label elements

Hazard symbol: No symbol.

Signal word: Not available.

Hazard statement: Not available.

Precautionary statement

Prevention: Not available.

Response: Not available.

Storage: Not available.

Disposal: Not available.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Mixture

Non-hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin Glargine</td>
<td></td>
<td>160337-95-1</td>
<td>94</td>
</tr>
<tr>
<td>OA-Arg-Insulin Glargine</td>
<td></td>
<td>No Data</td>
<td>6</td>
</tr>
</tbody>
</table>

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. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed: Not available.
Indication of immediate medical attention and special treatment needed

Treatment of overdose should be symptomatic and supportive and may include the following:
1. For mild to moderate hypoglycemia, administer orally a source of sugar (glucose gel, glucose tablets, fruit juice, corn syrup, non-diet soda, honey, sugar cubes, table sugar dissolved in water, or a glassful of orange juice). Monitor blood glucose levels.
2. For severe hypoglycemia, stabilize with IV dextrose, then administer a continuous infusion of dextrose injection to maintain slight hyperglycemia. Oral glucose cannot be relied on to maintain euglycemia.
3. Glucagon, administered intramuscularly, may be useful for fast onset of action to mobilize hepatic glucose stores but may be ineffective or variable in its effect if glycogen stores are depleted.
4. Monitor vital signs, arterial blood gasses, blood glucose, and serum electrolytes (especially calcium, potassium, and sodium) as required. Blood urea nitrogen and serum creatinine concentrations should also be checked.
5. Manage cerebral edema with mannitol and dexamethasone.
6. Manage hypokalemia with potassium supplements. [USP DI 2007]

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 spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and 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
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

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

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

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.

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

Exposure limit values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin Glargine (CAS 160337-95-1)</td>
<td>TWA</td>
<td>0.2 mg/m3</td>
</tr>
</tbody>
</table>

Biological limit values

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.
Individual protection measures, such as personal protective equipment

**Eye/face protection**
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Skin protection**
**Hand protection**
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact.
Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Other**
For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

**Respiratory protection**
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Thermal hazards**
Not available.

**General hygiene considerations**
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

**Appearance**
White powder.

**Physical state**
Solid.

**Form**
Powder.

**Odor**
Not available.

**Odor threshold**
Not available.

**pH**
Not available.

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

**Flash point**
Not available.

**Evaporation rate**
Not available.

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

**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 in water**
Not available.

**Partition coefficient (n-octanol/water)**
Not available.

**Decomposition temperature**
Not available.

**Viscosity**
Not available.

10. Stability and reactivity

**Reactivity**
No reactivity hazards known.

**Chemical stability**
Stable at normal conditions.

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

**Conditions to avoid**
None known.

**Incompatible materials**
Strong oxidizing agents.

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

11. Toxicological information

**Information on likely routes of exposure**

**Ingestion**
Due to lack of data the classification is not possible.
Inhalation
Due to lack of data the classification is not possible.

Skin contact
Due to lack of data the classification is not possible.

Eye contact
Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure
Insulin (by injection or inhalation): Hypoglycemia. Hypokalemia. Slow or irregular heartbeat. Central nervous system depression. Coma.

Medical conditions aggravated by exposure
Insulin (by injection or inhalation): Active alcoholism. Conditions causing food malabsorption. Adrenal or pituitary gland insufficiency. Hyperthyroidism. Kidney or liver impairment.

Acute toxicity
Due to lack of data the classification is not possible.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin Glargine (CAS 160337-95-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Skin corrosion/irritation</strong></td>
<td></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td><strong>Serious eye damage/eye irritation</strong></td>
<td></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td><strong>Respiratory sensitization</strong></td>
<td></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td><strong>Skin sensitization</strong></td>
<td></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td><strong>Sensitization</strong></td>
<td></td>
<td>There have been reports of anaphylactic reactions following therapeutic use of a component of this material</td>
</tr>
<tr>
<td><strong>Germ cell mutagenicity</strong></td>
<td></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td><strong>Mutagenicity</strong></td>
<td></td>
<td>Ames test in bacteria</td>
</tr>
<tr>
<td><strong>Insulin Glargine</strong></td>
<td></td>
<td>Result: Not mutagenic.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HGPRT test in mammalian cells</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: Not mutagenic.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In vitro cytogenetics test in Chinese hamster V79 cells</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: Not mutagenic.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In vivo cytogenetics test in Chinese hamster bone marrow cells</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: Not mutagenic.</td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Insulin Glargine</td>
<td>0.455 mg/day 2-year Carcinogenicity studies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: Benign skin tumors at injection sites in males.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td><strong>Reproductive toxicity</strong></td>
<td></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Maternal glucose and maternal insulin antibodies can cross the placenta and may cause excess insulin levels in the fetus. This may lead to abnormally large newborns that may require early induced or cesarean delivery.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reproductivity</strong></td>
<td></td>
<td>0 - 0.072 mg/kg/day Subcutaneous reproduction and teratology study, administered during organogenesis</td>
</tr>
<tr>
<td>Insulin Glargine</td>
<td></td>
<td>Result: Maternal hypoglycemia at high dose. No consistent and documentable embryotoxicity.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 - 0.36 mg/kg/day Subcutaneous reproduction and teratology study, administered during organogenesis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: No impairment of fertility. No increase in the incidence of malformations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td><strong>Specific target organ toxicity</strong></td>
<td></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td><strong>single exposure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Specific target organ toxicity</strong></td>
<td></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td><strong>repeated exposure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Aspiration hazard</strong></td>
<td></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
</tbody>
</table>
12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Daphnia magna</td>
</tr>
<tr>
<td>Other</td>
<td>EC50</td>
<td>Pseudokirchnerella subcapitata</td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>Zebra danio (Danio rerio)</td>
</tr>
</tbody>
</table>

Persistence and degradability
Readily biodegradable.

Bioaccumulative potential
Not available.

Mobility in soil
Not available.

Other adverse effects
Not available.

13. Disposal considerations

Disposal instructions
This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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.

Local disposal regulations
Not available.

Hazardous waste code
Not regulated.

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 a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.

15. Regulatory information

US federal regulations
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
No

SARA 311/312 Hazardous chemical
No

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
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

<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>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</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>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).

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

- **Issue date**: 06-28-2013
- **Version #**: 01
- **Further information**: Not available.
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