1. Identification

**Product identifier**
Insulin Glargine

**Other means of identification**

<table>
<thead>
<tr>
<th>Catalog number</th>
<th>1342059</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS number</td>
<td>160337-95-1</td>
</tr>
<tr>
<td>Synonyms</td>
<td>A21-Gly-B31-Arg-B32-Arg-insulin</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Company name</th>
<th>U. S. Pharmacopeia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>12601 Twinbrook Parkway Rockville MD 20852-1790 United States</td>
</tr>
<tr>
<td>Website</td>
<td><a href="http://www.usp.org">www.usp.org</a></td>
</tr>
<tr>
<td>E-mail</td>
<td><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a></td>
</tr>
<tr>
<td>Telephone</td>
<td>RS Technical Services 301-816-8129</td>
</tr>
</tbody>
</table>

**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.

**Environmental hazards**
Not classified.

**OSHA defined hazards**
Not classified.

**Label elements**

| Hazard symbol | None. |
| Signal word   | None. |
| Hazard statement | Not available. |

**Precautionary statement**

| Prevention | Not available. |
| Response   | Not available. |
| Storage    | Not available. |
| Disposal   | Not available. |

**Hazard(s) not otherwise classified (HNOC)**

This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

**Supplemental information**
Pharmacologically active material.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<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>A21-Gly-B31-Arg-B32-Arg-insulin</td>
<td>160337-95-1</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>
4. First-aid measures

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

**Skin contact**
Wash off with soap and water. 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**
Hypoglycemia. Pharmacologically active material. Occupational exposure may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically. Treatment of overdose may include the following: 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. 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. 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. 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. Manage cerebral edema with mannitol and dexamethasone. Manage hypokalemia with potassium supplements.

**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**
Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

**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. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

**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 deterrent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). 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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

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

Biological limit values

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

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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

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 lab coat. 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

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters 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

Handle in accordance with good industrial hygiene and safety practice. 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 descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Crystalline powder.

Color

White. Off-white.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

449.6 - 453.2 °F (232 - 234 °C)

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): Insoluble.
- Solubility (other): Dilute acids: Soluble.

Auto-ignition temperature: > 428 °F (> 220 °C)

Decomposition temperature: Not available.

Viscosity: Not available.

Other information:
- Dust explosion properties:
  - Minimum ignition energy (MIE) - dust cloud: 13 - 30 mJ

Molecular formula: C267H404N72O78S6
Molecular weight: 6062.9

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: NOx, SOx. 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

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin Glargine (CAS 160337-95-1)</td>
<td>Oral LD50 Rat</td>
<td>&gt; 2000 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.
Mutagenicity
Ames test
Result: Negative.
Chromosome aberration
Result: Negative.
Micronucleus test
Result: Negative.

Carcinogenicity
Knowledge about carcinogenicity is incomplete.
0.455 mg/day Carcinogenicity
Result: Benign skin tumors at injection sites in males.
Species: Rat
Test Duration: 2 years

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

Reproductivity
0 - 0.072 mg/kg/day Reproductivity, administered during organogenesis
Result: Maternal hypoglycemia at high dose. No consistent and documentable embryotoxicity.
Species: Rabbit
0 - 0.36 mg/kg/day Reproductivity, administered during organogenesis
Result: No impairment of fertility. No increase in the incidence of malformations.
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
Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Product</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>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>EC50</td>
<td>346.1 mg/l, 72 hours OECD 201</td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>&gt; 100 mg/l, 48 hours OECD 202</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>&gt; 100 mg/l, 96 hours OECD 203</td>
</tr>
</tbody>
</table>

Persistence and degradability
Readily biodegradable.

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
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.
This product is not known to be 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
Combustible dust

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
California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. 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>
<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>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>

*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 06-28-2013
Revision date 06-20-2019
Version # 04

Further information
Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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