1. Identification

Product identifier: Insulin Bovine

Other means of identification

Catalog number: 1342208
Chemical name: Insulin bovine
Synonym(s): Beef insulin

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin Bovine</td>
<td>Beef insulin</td>
<td>11070-73-8</td>
<td>100</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. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed

Indication of immediate medical attention and special treatment needed

Hypoglycemia.

Treatment of overdose should be symptomatic and supportive and 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. [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

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

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.

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. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. 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. Clean surface thoroughly to remove residual contamination.

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

Biological limit values

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

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

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. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

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).

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

9. Physical and chemical properties

Appearance
White or practically white crystalline powder.

Physical state
Solid.

Form
Powder.

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 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
Insoluble.

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

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information
Chemical family
Polypeptide hormone.

Molecular formula
C254H377N65O75S6

Molecular weight
5733.5

Solubility (other)
Practically insoluble in ethanol; soluble in dilute acids and in dilute alkalis.

10. Stability and reactivity

Reactivity
No reactivity hazards known.

Chemical stability
Material is stable under normal conditions.

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

Conditions to avoid
None known.

Incompatible materials
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**

- Anxiety
- Confusion
- Difficulty sleeping
- Slurred speech
- Blurred vision
- Sweating
- Pale skin
- Drowsiness
- Fast heartbeat
- Trembling
- Headache
- Nausea
- Yawning
- Tiredness
- Weakness
- Unconsciousness
- Seizures

**Delayed and immediate effects of exposure**

- Hypoglycemia
- Coma

**Medical conditions aggravated by exposure**

- Active alcoholism
- Food malabsorption disorders
- Hypoglycemia
- Hyperglycemia
- Lung disease
- Kidney disease
- Liver disease
- Hyperthyroidism

**Acute toxicity**

Due to lack of data the classification is not possible.

**Skin corrosion/irritation**

Due to lack of data the classification is not possible.

**Serious eye damage/eye irritation**

Due to lack of data the classification is not possible.

**Respiratory sensitization**

Due to lack of data the classification is not possible.

**Skin sensitization**

Due to lack of data the classification is not possible.

**Germ cell mutagenicity**

Due to lack of data the classification is not possible.

**Carcinogenicity**

Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

**Reproductive toxicity**

Due to lack of data the classification is not possible. Maternal glucose and maternal insulin antibodies can cross the placenta and may cause excess insulin levels in the fetus.

- **Reproductivity**
  - Reproductivity study
  - Result: Injection of two units into egg yolk sacs during incubation led to skeletal defects in the chicks.
  - Species: Chicken
  - Reproductivity study
  - Result: Twice daily doses of 0.5 units during the last two weeks of pregnancy did not cause birth defects.
  - Species: Rat

**Specific target organ toxicity - single exposure**

Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure**

Due to lack of data the classification is not possible.

**Aspiration hazard**

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

12. Ecological information

**Ecotoxicity**

No ecotoxicity data noted for the ingredient(s).

**Persistence and degradability**

No data is available on the degradability of this product.

**Bioaccumulative potential**

Not available.

**Mobility in soil**

Not available.

**Other adverse effects**

Not available.

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**

Not available.

**Hazardous waste code**

Not available.

**Waste from residues / unused products**

Dispose of in accordance with local regulations. 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
CERCLA/SARA Hazardous Substances - Not applicable.
One or more components are not listed on TSCA.

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

Country(s) or region | Inventory name | On inventory (yes/no)*
--- | --- | ---
Australia | Australian Inventory of Chemical Substances (AICS) | No
Canada | Domestic Substances List (DSL) | Yes
Canada | Non-Domestic Substances List (NDSDL) | No
China | Inventory of Existing Chemical Substances in China (IECSC) | No
Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | Yes
Europe | European List of Notified Chemical Substances (ELINCS) | No
Japan | Inventory of Existing and New Chemical Substances (ENCS) | No
Korea | Existing Chemicals List (ECL) | No
New Zealand | New Zealand Inventory | Yes
Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No
United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No

* 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 05-01-2014
Revision date 05-01-2014
Version # 03
Further information Not available.
Disclaimer

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

Revision Information

Composition / Information on Ingredients: Disclosure Overrides
First-aid measures: Most important symptoms/effects, acute and delayed
Physical & Chemical Properties: Multiple Properties
Toxicological information: Reproductive toxicity
Disposal considerations: Disposal instructions