

Material Safety Data Sheet

INSULIN HUMAN

Date: August 26, 2010

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Human Insulin

Product Use: Human Insulin IP Reference Standard is used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

Adverse Effects: Adverse effects following injection of insulin or inhalation of powder may include mild hypoglycemia (anxiety, confusion, difficulty concentrating, sleep difficulties, abnormal behavior, slurred speech, blurred vision, sweating, cool pale skin, drowsiness, hunger, fast or pounding heartbeat, trembling, headache, nausea, uncontrolled yawning, unusual tiredness or weakness) and weight gain. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Excessive doses of insulin are associated with severe hypoglycemia (disorientation, unconsciousness, seizures, coma, and death), nausea, vomiting, and diarrhea.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation and severe hypoglycemia.

Chronic: Possible hypersensitization and drug tolerance. Prolonged hypoglycemia may cause irreversible damage to brain.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material; active alcoholism; conditions causing food malabsorption (diarrhea, gastroparesis, intestinal obstruction, vomiting); conditions causing hypoglycemia (adrenal or pituitary gland insufficiency); conditions causing hyperglycemia (female hormonal changes, severe infection, high fever, stress); surgery, injury, or trauma; lung, kidney, or liver disease; and uncontrolled hyperthyroidism

Cross Sensitivity: n/f

Target Organs: Liver and kidneys

For additional information on toxicity, see Section 11

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Common Name: Insulin Human

Chemical Name: Insulin (human)

Formula: C₂₅₇H₃₈₃N₆₅O₇₇S₆

Molecular Weight: 5807.58

Synonym: n/f

CAS: 11061-68-0

Chemical Family: Polypeptide hormone

Therapeutic Category: Antidiabetic

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: Not absorbed through the skin. May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water. This material is inactivated in the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If n/f = not found

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person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: 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.

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately-labelled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

Handling: As a general rule, when handling IP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight container as defined in the IP Insulin monograph. This material should be handled and stored per label instructions to ensure product integrity. Hygroscopic. Store in a freezer. Allow container to reach room temperature before opening.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: Industry: 12-hr TWA 120 micrograms/m³; 15-min STEG 600 micrograms/m³

n/f = not found

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SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the IP Reference Standard Lot provided.

Appearance and Odor: White or practically white crystals; odorless or slight odor

Odor Threshold: n/f

pH: n/f

Melting Range: n/f

Boiling Point: n/f

Flash Point: n/f

Autoignition Temp: n/f

Evaporation Rate: n/f

Vapor Pressure: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Practically insoluble

Fat Solubility: n/f

Partition Coefficient: n-octanol/ water: n/f

Percent Volatile: n/f

Other Solubility: Practically insoluble in ethanol, ether, and chloroform; soluble in dilute mineral acids

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to light, heat, and moisture.

Incompatibilities: Strong oxidizing agents

Decomposition Products: When heated to decomposition n material emits toxic fumes of NOx and SOx. Emits toxic fumes under fire conditions.

Stable: Yes

Hazardous Polymerization: No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: n/f

Oral Mouse: LD50: n/f

Irritancy Data: n/f

Corrosivity: n/f

Other Toxicity Data: Intravenous Rat LD50: 145 mg/kg

Sensitization Data: n/f

Listed as a Carcinogen by: NTP: No IARC: No OSHA: No

Other Carcinogenicity Data: There was no evidence of carcinogenicity in a one-year study in rats given subcutaneous injections of insulin

Mutagenicity Data: Human insulin was not mutagenic in mammalian cells and tested negative in the Ames bacterial reverse mutation assay with and without activation

n/f = not found

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Reproductive and Developmental Effects: 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. In rats, twice daily doses of 0.5 units of insulin during the last two weeks of pregnancy did not cause birth defects. Injection of two units of insulin into chicken egg yolk sacs during incubation led to skeletal defects in the chicks

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Country laws and regulations.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

Indian Pharmacopoeia 2010, Product monograph of US Pharmacopoeia, British Pharmacopoeia, European Pharmacopoeia

SECTION 16 - OTHER INFORMATION

- As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel.
- References: USP Insulin Human Product Material Safety Data Sheet
- Read product leaflet for Catalogue No. Insulin HI-01 before use.

n/f = not found

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