

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078435038

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078438053

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078520437



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Humulin®</b>		
<b>Other means of identification</b>			
<b>Item Code</b>	HP8824, CS0993, CS0994, CS0995, HI0509, B02136, HI0010, HI0040, HI0080, HI0210, HI0211, HI0212, HI0213, HI0217, HI0218, HI0219, HI0240, HI0241, HI0242, HI0280, HI0310, HI0312, HI0313, HI0314, HI0317, HI0318, HI0319, HI0340, HI0412, HI0414, HI0417, HI0418, HI0419, HI0440, HI0442, HI0480, HI0500, HI0610, HI0612, HI0617, HI0619, HI0640, HI0710, HI0713, HI0714, HI0717, HI0718, HI0719, HI0740, HI0810, HI0814, HI0817, HI0818, HI0819, HI0840, HI0910, HI0914, HI0917, HI0918, HI0919, HI0940, HI1510, HI1514, HI1517, HI1518, HI1519, HI1540, HI1610, HI1614, HI1617, HI1618, HI1619, HI1640, HP8120, HP8130, HP8150, HP8160, HP8170, HP8180, HP8190, HP8720, HP8730, HP8750, HP8760, HP8770, HP8780, HP8790, HP8803, HP8804, HP8805, MS8094, MS8095, MS8305, MS8306, ND1041, ND1042, ND1043, ND1044, ND1045, ND1046, VF0103, VF0104, VF0105, VF0106, VF0107, VF0108, VF0109, VF0110, VF0111, VF0116, VF0117, VF0147, VF0148, VF0149, VF0150, VF0179, VF0183, VF0228, VF0229, VL7613, VL7614, VL7615, ZD0070		
<b>Recommended use</b>	Pharmaceutical		
<b>Recommended restrictions</b>	None known.		
<b>Manufacturer/Importer/Supplier/Distributor information</b>			
<b>Manufacturer</b>			
<b>Company name</b>	Eli Lilly and Company		
<b>Address</b>	Lilly Corporate Center Indianapolis, IN 46285 United States		
<b>Telephone</b>	Phone:	+1-317-276-2000	
<b>E-mail</b>	lilly_msds@lilly.com		
<b>Emergency phone number</b>	CHEMTREC:	+1-800-424-9300	

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement</b>	
<b>Prevention</b>	Not available.
<b>Response</b>	Not available.
<b>Storage</b>	Not available.
<b>Disposal</b>	Not available.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Not applicable.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Zinc-Insulin Crystals Human		11061-68-0	0.1 - 0.4

**Composition comments** Product contains ≤ 0.3% m-cresol and phenol. Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

## 4. First-aid measures

<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF exposed or concerned: Get medical advice/attention.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.
<b>Eye contact</b>	Immediately flush eye(s) with plenty of water. Get medical attention.
<b>Ingestion</b>	No hazards which require special first aid measures.
<b>Most important symptoms/effects, acute and delayed</b>	None known.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Use extinguishing media appropriate for surrounding fire.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	None known.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>General fire hazards</b>	This product is an aqueous mixture which will not burn.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Avoid inhalation of mists or aerosols.
<b>Methods and materials for containment and cleaning up</b>	Prevent runoff from entering drains, sewers, or streams. Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum.
<b>Environmental precautions</b>	Avoid release to the environment.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.
<b>Conditions for safe storage, including any incompatibilities</b>	Keep refrigerated. Do not allow material to freeze.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### Lilly (LEG)

#### Components

	Type	Value	Form
Insulin, Lispro Crystals (CAS 133107-64-9)	STEG (15min)	600 ug/m3	Respirable
	TWA (12hrs)	120 ug/m3	Respirable

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemical resistant gloves.
<b>Other</b>	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
<b>Respiratory protection</b>	If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an approved respirator with sufficient protection factor to control exposure below the OEL.
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material.

## 9. Physical and chemical properties

### Appearance

Physical state	Liquid.
Form	Liquid.
Color	Clear.

**Odor** Odorless

**Odor threshold** Not available.

**pH** 7 - 7.8

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** > 212 °F (> 100 °C)

**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(ies)

**Solubility (water)** Slightly soluble

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

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

### Other information

**Explosive properties** Not explosive

**Oxidizing properties** The substance or mixture is not classified as oxidizing.

**Specific gravity** 1.004 - 1.008

## 10. Stability and reactivity

**Reactivity** Not water reactive.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** Hazardous polymerization does not occur.

**Conditions to avoid** None under normal conditions.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

## 11. Toxicological information

### Information on toxicological effects

**Acute toxicity** Not expected to be active orally.

**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 or skin sensitization

**Respiratory sensitization** Due to lack of data the classification is not possible.

**Skin sensitization** Rhesus monkeys, extremely weak immunogenic potential. (Insulin, Lispro Crystals)  
Due to inconclusive data the classification is not possible.

**Germ cell mutagenicity** Results in genetic toxicity assays (in vitro): Negative (Insulin, Lispro Crystals)  
Due to inconclusive data the classification criteria are not met.

**Carcinogenicity** One-year subcutaneous injection studies demonstrated no evidence of carcinogenicity in rats. (Insulin, Lispro Crystals)  
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.  
Based on available data, the classification criteria are not met.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

**Reproductive toxicity** Mixed results reported in animal studies. Effects were attributed to hypoglycemia. Insulin itself is not considered a reproduction hazard. (Insulin, Lispro Crystals)  
Based on available data, the classification criteria are not met.

**Specific target organ toxicity - single exposure** Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure** Animal studies have reported the following effects: Decreased blood sugar levels. (Subcutaneous) (Insulin, Lispro Crystals)  
Based on available data, the classification criteria are not met.

**Aspiration hazard** No aspiration toxicity classification

**Further information** Insulin is a naturally occurring hormone. May cause decreased blood sugar levels with intravenous or subcutaneous administration. Symptoms typically associated with low blood sugar may include shakiness, sweating, fatigue, hunger, irritability, confusion, and rapid heartbeat.

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available for this product.

**Mobility in soil** No data available.

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** Dispose of contents/container in accordance with local/regional/national/international regulations.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not available.

## 15. Regulatory information

**US federal regulations** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

