

SAFETY DATA SHEETS

This SDS packet was issued with item:

078438053

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

078435038

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

Product identifier	Humulin®
Other means of identification	
Item Code	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
Recommended use	Pharmaceutical
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company name	Eli Lilly and Company
Address	Lilly Corporate Center Indianapolis, IN 46285 United States
Telephone	Phone: +1-317-276-2000
E-mail	lilly_msds@lilly.com
Emergency phone number	CHEMTREC: +1-800-424-9300

2. Hazard(s) identification

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

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

5. Fire-fighting measures

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

6. Accidental release measures

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

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.
Conditions for safe storage, including any incompatibilities	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

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.
Skin protection	
Hand protection	Chemical resistant gloves.
Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	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.
Thermal hazards	Not available.
General hygiene considerations	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.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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 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 Not regulated.
(SDWA)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	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)

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 05-16-2016

Revision date 07-06-2017

Version # 04

List of abbreviations TWA: Time Weighted Average STEL: Short Term Exposure Limit

Disclaimer 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 MERCHANT ABILITY 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. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
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Revision information First-aid measures: Ingestion
 Physical and chemical properties: Color