



SAFETY DATA SHEET

1. Identification

Product identifier	Humulin®
Other means of identification	
Item Code	HI0509, HP8805, HP8804, HP8803, HI0213, HI0313, HI0319, HI0810, HI0440, HI0217, HI1519, HI0819, MS8305, MS8306, HI0210, HI0740, HI1517, HI0817, HI0917, HI0940, HI0710, HI1610, HI0317, HI1640, HI1540, HI0840, VL7614, VL7613, HI0340, HP8770, HI0219, HI0640, HI0719, HI0310, HI0610, HI0240, HP8780, HI0500, HP8730, HI0410, HP8120, HI0717, HP8180, ND1044, ND1042, HP8720, ND1045, HP8130, ND1046, HP8190, ND1043, ND1041, HI0919, HI1510, HI0910, HI1617, VL7615, HI0412, HI0314, VF0229, HI0617, HI0619, HI1618, HP8750, HI0212, HI0241, HI0242, HI0280, HI0312, HI0419, HI0010, HI0040, HI0218, HI0318, HI0918, HI0380, HI0414, HI0417, HI0418, HI0342, HI0718, VF0148, HI0714, HI0442, HI0480, HI0612, HI0814, HI0818, HI1518, HP8170, HI0080, VF0147, VF0104, VF0105, VF0107, VF0108, VF0109, VF0110, VF0111, HP8790, VF0116, VF0228, VF0017, VF0149, VF0183, VF0106, HI1614, VF0103, MS8094, MS8095, HI0211, HI1514, HI0914, BO2136, BO1967, VF0179, HP8160, HI1619, HP8150, VF0150, HP8760, HI0713
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

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

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

DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.

Composition comments Product contains <0.3% m-cresol and phenol.
The full text for all R- and H-phrases is displayed in section 16.

4. First-aid measures

Inhalation Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.

Skin contact Wash off immediately with plenty of water for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.

Eye contact Immediately flush eye(s) with plenty of water. Get medical attention.

Ingestion Consult a physician.

Most important symptoms/effects, acute and delayed Not available.

5. Fire-fighting measures

Suitable extinguishing media Use extinguishing agent suitable for type of surrounding fire.

Unsuitable extinguishing media Not available.

Specific hazards arising from the chemical Hazardous decomposition products formed under fire conditions.

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

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

Occupational exposure limits No exposure limits noted for ingredient(s).

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

Exposure guidelines

US - Tennessee OELs: Skin designation

m-Cresol (CAS 108-39-4) Can be absorbed through the skin.

Phenol (CAS 108-95-2)

Can be absorbed through the skin.

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

Wear goggles/face shield.

Skin protection

Hand protection

Chemical resistant gloves.

Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection

Use an approved respirator. Select respirator with appropriate protection factor. Select appropriate respirator for physical characteristics of material.

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

Physical state

Liquid.

Form

Liquid.

Color

practically white

Odor

Odorless

Odor threshold

No data available.

pH

7 - 7.8

Melting point/freezing point

No data available.

Initial boiling point and boiling range

> 212 °F (> 100 °C)

Flash point

No data available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

No data available.

Flammability limit - upper (%)

No data available.

Explosive limit - lower (%)

No data available.

Explosive limit - upper (%)

No data available.

Vapor pressure

No data available.

Vapor density

No data available.

Relative density

No data available.

Solubility(ies)

Solubility (water)

Slightly soluble.

Partition coefficient (n-octanol/water)

No data available.

Auto-ignition temperature

No data available.

Decomposition temperature

No data available.

Viscosity

No data available.

Other information

Density

No data available.

Explosive properties

Not explosive

Oxidizing properties

The substance or mixture is not classified as oxidizing.

Specific gravity

1.004 - 1.008

VOC (Weight %)

No data available.

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	Hazardous decomposition products formed under fire conditions.

11. Toxicological information

Information on toxicological effects

Acute toxicity Not expected to be active orally.

Components	Species	Test Results
Insulin, Lispro Crystals (CAS 133107-64-9)		
Acute		
Other		
	Dog	2 units/kg, Subcutaneous 0.1 units/kg, Intravenous
	Rat	10 units/kg, Intravenous 10 units/kg, Subcutaneous

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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 No significant and/or relevant adverse effects reported.
Based on available data, the classification criteria are not met.

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. The following adverse effects have been noted with therapeutic use of this material: Hypersensitivity reactions.

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 Not available.
Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable 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)

m-Cresol (CAS 108-39-4) Listed.

Phenol (CAS 108-95-2) Listed.

SARA 304 Emergency release notification

Phenol (CAS 108-95-2) 1000 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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

m-Cresol (CAS 108-39-4)

Phenol (CAS 108-95-2)

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

US - California Candidate Chemicals: Listed

Phenol (CAS 108-95-2)

US - California Candidate Chemicals: Listed on initial list

m-Cresol (CAS 108-39-4)

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

m-Cresol (CAS 108-39-4)
 Phenol (CAS 108-95-2)

US. New Jersey Worker and Community Right-to-Know Act

m-Cresol (CAS 108-39-4)
 Phenol (CAS 108-95-2)

US. Pennsylvania Worker and Community Right-to-Know Law

m-Cresol (CAS 108-39-4)
 Phenol (CAS 108-95-2)

US. Rhode Island RTK

m-Cresol (CAS 108-39-4)
 Phenol (CAS 108-95-2)

US. California Proposition 65

Not Listed.

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 02-16-2015
Version # 01
Lilly Lab Code Health: 0
 Fire: 0
 Reactivity: 0

List of abbreviations

LEG: Lilly Exposure Guideline
 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 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. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
 Eli Lilly and Company
 Hazard Communication
 +1-317-651-9533

Revision Information

Product and Company Identification: Alternate Trade Names
 Hazard(s) identification: Disposal
 Hazard(s) identification: Prevention
 Hazard(s) identification: Response
 Hazard(s) identification: Storage
 Physical & Chemical Properties: Multiple Properties
 Other information, including date of preparation or last revision: List of abbreviations