Lilly

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,

VF0228, VF0229, VL7613, VL7614, VL7615, ZD0070

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, VF0111, VF0111, VF0116, VF0117, VF0147, VF0148, VF0149, VF0150, VF0179, VF0183,

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	<u></u>					
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.							

Material name: Humulin®

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

Unsuitable extinguishing

media

Use extinguishing media appropriate for surrounding fire.

None known.

Specific hazards arising from

the chemical

None known.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

General fire hazardsThis 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

_		-			_	-		_	_	 -	_	_	 -	_	
	L	il.	١	,	(l		E	G)						

Components	Туре	Value	Form
Insulin, Lispro Crystals (CAS 133107-64-9)	STEG (15min)	600 ug/m3	Respirable
(5.15.15.15.15.7)	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.

Material name: Humulin® SDS US

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 > 212 °F (> 100 °C)

range

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 solublePartition coefficientNot available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot 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 Hazardous polymerization does not occur.

reactions

Conditions to avoid None under normal conditions.

Incompatible materials Strong oxidizing agents.

Hazardous decompositionNo hazardous decomposition products are known.

products

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

Due to lack of data the classification is not possible.

irritation

Material name: Humulin® SDS US

6389 Version #: 04 Revision date: 07-06-2017 Issue date: 05-16-2016

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.

Results in genetic toxicity assays (in vitro): Negative (Insulin, Lispro Crystals) Germ cell mutagenicity

Due to inconclusive data the classification criteria are not met.

One-year subcutaneous injection studies demonstrated no evidence of carcinogenicity in rats. Carcinogenicity

(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

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

Specific target organ toxicity repeated exposure

(Insulin, Lispro Crystals)

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

No aspiration toxicity classification **Aspiration hazard**

Further information Insulin is a naturally occurring hormone. May cause decreased blood sugar levels with

Due to lack of data the classification is not possible.

intravenous or subcutaneous administration. Symptoms typically associated with low blood sugar may include shakiness, sweating, fatigue, hunger, irritability, confusion, and rapid heartbeat.

Animal studies have reported the following effects: Decreased blood sugar levels. (Subcutaneous)

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

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

No data available for this product. Bioaccumulative potential

No data available. Mobility in soil 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 Not available.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard US federal regulations

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.

Material name: Humulin® SDS US

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 regionInventory nameOn inventory (yes/no)*CanadaDomestic 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:

Eli Lilly and Company Hazard Communication +1-317-651-9533

Revision information First-aid measures: Ingestion

Physical and chemical properties: Color

Material name: Humulin® SDS US