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

LY Number LY41001

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 nameCommon name and synonymsCAS number%Zinc-Insulin Crystals Human11061-68-00.1 - 0.4

Material name: Humulin®

Product contains ≤ 0.3% m-cresol and phenol. Composition comments

Remaining components of this product are non-hazardous and/or are present at concentrations

below reportable levels.

4. First-aid measures

Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF exposed or Inhalation

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.

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

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

Wear suitable protective equipment.

and precautions for firefighters 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	Туре	Value	Form	
Insulin, Lispro Crystals (CAS 133107-64-9)	STEG (15min)	600 ug/m3	Respirable	
	TWA (12hrs)	120 ug/m3	Respirable	
ological limit values	No biological exposure limits noted for the ingredient(s).			

Appropriate engineering

Open handling is not recommended. Use appropriate control measures such as fume hood.

controls

ventilated enclosure. local exhaust ventilation, or down-draft booth.

Individual protection measures, such as personal protective equipment

Safety glasses with side shields recommended. If splash potential or dusty operations, wear Eye/face protection

goggles/faceshield.

Skin protection

Hand protection Chemical resistant gloves.

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

If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an Respiratory protection

approved respirator with sufficient protection factor to control exposure below the OEL.

Thermal hazards Not available.

Material name: Humulin® SDS US 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

Liquid. Physical state Liquid. **Form** Color Clear. Odorless Odor **Odor threshold** Not available.

7 - 7.8 pН

Melting point/freezing point Not available. > 212 °F (> 100 °C)

Initial boiling point and boiling

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. Not available. Explosive limit - upper (%) Vapor pressure Not available. Vapor density Not available. Relative density Not available.

Solubility(ies)

Slightly soluble Solubility (water) Not available. Partition coefficient

(n-octanol/water)

Auto-ignition temperature Not available. **Decomposition temperature** Not available. **Viscosity** Not available.

Other information

Not explosive. **Explosive properties**

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

1.004 - 1.008 Specific gravity

10. Stability and reactivity

Not water reactive. Reactivity

Material is stable under normal conditions. Chemical stability Possibility of hazardous Hazardous polymerization does not occur.

reactions

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.

Material name: Humulin® SDS US 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 Crvstals)

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 1910.1001-1052)

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 instructionsDispose 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

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.

Material name: Humulin®

Toxic Substances Control Act (TSCA)

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 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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.

International Inventories

Country(s) or regionInventory nameOn inventory (yes/no)*CanadaDomestic Substances List (DSL)NoCanadaNon-Domestic Substances List (NDSL)NoUnited States & Puerto RicoToxic Substances Control Act (TSCA) InventoryNo

16. Other information, including date of preparation or last revision

 Issue date
 05-16-2016

 Revision date
 02-19-2019

Version # 05

List of abbreviations TWA: Time Weighted AverageSTEL: 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 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

Material name: Humulin® SDS US

^{*}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).