



SAFETY DATA SHEET

1. Identification

Product identifier	Humalog®
Other means of identification	
Item Code	ZZ0090, HP7712, CT5585, ND1048, ND1026, HP8794, VL7394, VL7515, VL7392, ND1025, VL7395, VL7393, HP8797, HP8799, HP8793, ND1037, HP8798, HP8194, HP8191, HP8791, HP8725, VL7391, VL7516, VL7513, VL7512, VL7511, VL7510, VL7514, VL7517, HP8193, HP8125, B01966, HP8801, ND1049, VL7533, VL7396, VL7662, BL7394
Synonyms	Humalog * Insulin (human), 28B-L-lysine-29B-L-proline- * Lys(B28), Pro(B29) human insulin analog
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	%
Insulin, Lispro Crystals	Insulin (human), 28B-L-lysine-29B-L-proline-Lys(B28), Pro(B29) human insulin analog	133107-64-9	0.7

Composition comments	Product contains \leq 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 to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
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	Consult a physician.
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.

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG)

Components

Insulin, Lispro Crystals
(CAS 133107-64-9)

Type

STEG (15min)

TWA (12hrs)

Value

600 ug/m3

120 ug/m3

Form

Respirable

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	Colorless.

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	No data 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)	Soluble (water)
--------------------	-----------------

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.
Percent volatile	No data available.
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	No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Insulin, Lispro Crystals (CAS 133107-64-9)		
<u>Acute</u>		
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) Based on available data, the classification criteria are not met.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not available.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not available.		
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	
12. Ecological information		
Ecotoxicity	No data available.	
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 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

Not regulated.

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

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

US. Rhode Island RTK

Not regulated.

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 12-05-2014
Revision date 09-25-2015
Version # 04
Lilly Lab Code Health: 0
Fire: 0
Reactivity: 0

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 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