



SAFETY DATA SHEET

1. Identification

| | | | |
|---|--|-----------------|--|
| Product identifier | Humalog® | | |
| Other means of identification | | | |
| Item Code | 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 | 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 | 0.35 |
| 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

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| 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

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|---|--|
| 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

| | 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).

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.

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

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|---|--|
| 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) | | |
| Acute <i>Other</i> | | |
| | 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.

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 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.

Waste codes D024: Waste m-Cresol
U188: Waste Phenol

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 This substance/mixture is not intended to be transported in bulk.

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 |

| | | |
|-----------------------------|---|-------------------------------|
| Country(s) or region | Inventory name | On inventory (yes/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 |
| Version # | 01 |
| Lilly Lab Code | Health: 0 Fire: 0 Reactivity: 0 |

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

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|-------------------|--|
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