



SAFETY DATA SHEET

1. Identification

| | |
|---|--|
| Product identifier | Lyumjev™ |
| Other means of identification | |
| Item Code | 700771, 702325, 702189, 700774, 700873, VL7735, 700852, VL7728, VL7726, HP8228, HP8209, HP8207, 700744, 700741, 700772, 700773, CT2076, 700861, 700743, 700746, 700776, CT2074, 700775, 700747, CT2079, 700748, 700774, 700844, 703158, CT9568 |
| Synonyms | LY275585 Injection with Treprostinil * Lispro Insulin Injection with Treprostinil * URI Vaso-CE |
| LY Number | LY900014 |
| 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_sds@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 | None. |

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 |
| Treprostinil | | 81846-19-7 | 0.0001 |

| | |
|-----------------------------|---|
| Composition comments | Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels. Product contains < 0.5% m-Cresol. |
|-----------------------------|---|

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 immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists. |
| Eye contact | In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention. |
| Ingestion | Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately. |
| Most important symptoms/effects, acute and delayed | None known. |
| Indication of immediate medical attention and special treatment needed | None known. |

5. Fire-fighting measures

| | |
|--|---|
| Suitable extinguishing media | Use fire-extinguishing media appropriate for surrounding materials. |
| Unsuitable extinguishing media | Not available. |
| Specific hazards arising from the chemical | Not applicable. |
| 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

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|--|---|
| Personal precautions, protective equipment and emergency procedures | Avoid inhalation of mists or aerosols. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment. |
| Methods and materials for containment and cleaning up | Stop the flow of material, if this is without risk. Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |

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 container tightly closed in a dry and well-ventilated place. |

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).

Exposure guidelines

(Trepstinil) A Lilly exposure guideline has not been established. Preliminary guidance: Control exposures to less than 1 ug/m3 until an OEL is established.
Manufacturer: Occupational Exposure Limit (OEL): 0.5 mcg/m3 8 hour TWA

Appropriate engineering controls

Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, isolator (i.e. glove bag/glove box) and/or closed transfers to maintain airborne levels below occupational exposure level (OEL).

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. If material is handled in a fume hood or ventilated enclosure, consider using redundant respiratory protection. |
| 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 | Aqueous Solution |
| Color | Clear, Colorless |
| Odor | Not available. |
| Odor threshold | Not available. |
| pH | 7 - 7.8 |
| Melting point/freezing point | Not available. |
| Initial boiling point and boiling range | Not available. |
| 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) | Soluble in water. |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Explosive properties | Not explosive. |
| Oxidizing properties | No oxidizing properties. |

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 known. |
| Incompatible materials | Strong oxidizing substances. |
| Hazardous decomposition products | None 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, Subcutaneous 10 units/kg, Intravenous |
| Trepstinil (CAS 81846-19-7) | | |
| <u>Acute</u> | | |
| LD50 | Rat | 71 mg/kg (intravenous, female) 56 mg/kg (intravenous, male) |
| Oral | | |
| LD50 | Mouse | 140 mg/kg (female) 134 mg/kg (male) |
| | Rat | 114 mg/kg (male) 92 mg/kg (female) |
| Skin corrosion/irritation | Causes skin irritation. (Trepstinil) Based on available data, the classification criteria are not met. | |
| Serious eye damage/eye irritation | Causes serious eye irritation. (Trepstinil) Based on available data, the classification criteria are not met. | |
| 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) No data available for remaining ingredients. Due to partial or complete lack of data the classification is not possible. | |
| Germ cell mutagenicity | Results in genetic toxicity assays (in vitro): Negative (Insulin, Lispro Crystals) In vitro and in vivo tests did not show mutagenic effects. (Trepstinil) Due to inconclusive data the classification is not possible. | |
| Carcinogenicity | No effects identified in animal studies. (Insulin, Lispro Crystals) (Trepstinil) Based on available data, the classification criteria are not met. | |
| IARC Monographs. Overall Evaluation of Carcinogenicity | | |
| Not listed. | | |
| OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053) | | |
| Not listed. | | |
| 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) Experiments have shown reproductive toxicity effects on laboratory animals. (Trepstinil Diolamine) Based on available data, the classification criteria are not met. | |
| Specific target organ toxicity - single exposure | May cause respiratory irritation. (Trepstinil) 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) Causes damage to organs (Respiratory Tract, Heart) through prolonged or repeated exposure by inhalation. (Trepstinil) 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. (Insulin, Lispro Crystals)
Effects reported with therapeutic administration: Headache. Flushing. Nausea, vomiting. (Treprostinil)

12. Ecological information

Ecotoxicity This material has not been tested for environmental effects.

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

Bioaccumulative potential No data available on bioaccumulation.

Partition coefficient n-octanol / water (log Kow)

| | |
|--------------|--|
| Treprostinil | 0.43, (pH 8 and 10) 1.4, (pH 6) 1.7, (pH 2) 2, (pH 4) |
|--------------|--|

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.

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 1910.1001-1053)

Not listed.

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 region | Inventory name | On inventory (yes/no)* |
|----------------------|--------------------------------|------------------------|
| Canada | Domestic Substances List (DSL) | No |

| Country(s) or region | Inventory name | On inventory (yes/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 04-22-2020

Revision date 07-30-2020

Version # 02

List of abbreviations
ACGIH: American Conference of Governmental Industrial Hygienists.
DOT: Department of Transportation (49 CFR 172.101).
IARC: International Agency for Research on Cancer.
IATA: International Air Transport Association.
IMDG Code: International Maritime Dangerous Goods Code.
LEG: Lilly Exposure Guideline.
LD50: Lethal Dose 50%.
NIOSH: National Institute for Occupational Safety & Health.
OSHA: Occupational Safety & Health Administration.
STEG: Short Term Exposure Guideline.
TWA: Time Weighted Average Value.

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:
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Revision information First-aid measures: Indication of immediate medical attention and special treatment needed