



SAFETY DATA SHEET

1. Identification

| | |
|--------------------------------------|------------------------------------------------------------------------------------------------|
| Product identifier | Basaglar® |
| Other means of identification | |
| Item Code | 703147, 703030, 515568, 513350, VL7667, 703195, 700580, 703148, HP7715, HP7711, VL7661, CT7661 |
| LY Number | LY2963016 |
| 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 | None. |

3. Composition/information on ingredients

Mixtures

| Chemical name | Common name and synonyms | CAS number | % |
|----------------------|---------------------------------------------------------|-------------------|------------|
| Insulin Glargine | IUPAC: 21A-Gly-30Ba-L-Arg-30Bb-L-Arg insulin (human) | 160337-95-1 | 0.36 - 0.7 |

| | |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Composition comments | Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels. Product contains < 0.3% m-Cresol. |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|

4. First-aid measures

| | |
|---------------------|------------------------------------------------------------------------------------------|
| Inhalation | Move to fresh air. Call a physician if symptoms develop or persist. |
| Skin contact | Wash off with soap and water. Get medical attention if irritation develops and persists. |
| Eye contact | Rinse with water. Get medical attention if irritation develops and persists. |
| Ingestion | Get medical attention if symptoms occur. |

Most important symptoms/effects, acute and delayed Decreased blood sugar levels.

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

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.

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 Glargine (CAS 160337-95-1)

Type

STEG (15min)

TWA (12hrs)

Value

600 ug/m3

120 ug/m3

Form

(respirable dust)

(respirable dust)

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

Phenolic.

Odor threshold

Not available.

| | |
|-----------------------------------------------------|----------------------------------------------------------|
| pH | 4 |
| 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 | The substance or mixture is not classified as oxidizing. |
| Specific gravity | 1.004 |

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 | Not expected to be active orally. |
| 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 | Due to lack of data the classification is not possible. |
| Germ cell mutagenicity | In vitro and in vivo tests did not show mutagenic effects. Based on available data, the classification criteria are not met. |
| Carcinogenicity | Not listed by IARC, NTP, ACGIH or OSHA. Due to lack of data the classification is not possible. |

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 | Animal testing did not show any effects on fertility. Animal testing did not show any effects on foetal development. Based on available data, the classification criteria are not met. |
| Specific target organ toxicity - single exposure | Decreased blood sugar levels. Based on available data, the classification criteria are not met. |
| Specific target organ toxicity - repeated exposure | No significant target organ toxicity reported. Based on available data, the classification criteria are not met. |
| Aspiration hazard | Not applicable. |
| Further information | Decreased blood sugar levels. Symptoms typically associated with low blood sugar may include shakiness, sweating, fatigue, hunger, irritability, confusion, and rapid heartbeat. |

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 on bioaccumulation. |
| 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. |
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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.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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 12-18-2015

Revision date 02-26-2019

Version # 04

List of abbreviations
LEG: Lilly Exposure Guideline.
STEG: Short Term Exposure Guideline.
TWA: Time Weighted Average

Disclaimer
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For additional information contact:
Eli Lilly and Company
Hazard Communication
+1-317-651-9533