



SAFETY DATA SHEET

1. Identification

Product identifier	Basaglar®
Other means of identification	
Item Code	CT7715, 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_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 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.
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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 1910.1001-1053)

Not listed.

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.
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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 1910.1001-1053)

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.

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 04-16-2020

Version # 05

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: International Maritime Dangerous Goods Code
LEG: Lilly Exposure Guideline.
OSHA: Occupational Safety & Health Administration.
PBT: Persistent, bioaccumulative, toxic.
STEG: Short Term Exposure Guideline.
TWA: Time Weighted AveragePvB: very Persistent, very Bioaccumulative.

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 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

Revision information

Product and Company Identification: Product Codes
Other information, including date of preparation or last revision: Disclaimer
Other information, including date of preparation or last revision: List of abbreviations