



SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture Abasaglar®
Registration number -
Synonyms None.
Item Code 703147, 703030, 515568, 513350, VL7667, 703195, 700580, 703148, HP7715, HP7711, VL7661, CT7661

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Pharmaceutical
Uses advised against None known.

1.3. Details of the supplier of the safety data sheet

Supplier

Company name Eli Lilly and Company
Address Lilly Corporate Center
Indianapolis, IN 46285
United States

Division

Telephone Phone: +1-317-276-2000
e-mail lilly_msds@lilly.com

1.4. Emergency telephone number CHEMTREC: 00 +1 + 703-527-3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains: Insulin Glargine
Hazard pictograms None.
Signal word None.
Hazard statements The mixture does not meet the criteria for classification.

Precautionary statements

Prevention Not available.
Response Not available.
Storage Not available.
Disposal Not available.

Supplemental label information None.

2.3. Other hazards None known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

| Chemical name | % | CAS-No. / EC No. | REACH Registration No. | INDEX No. | Notes |
|---------------|---|------------------|------------------------|-----------|-------|
|---------------|---|------------------|------------------------|-----------|-------|

| | | | | | |
|------------------|------------|-------------|---|---|--|
| Insulin Glargine | 0,36 - 0,7 | 160337-95-1 | - | - | |
|------------------|------------|-------------|---|---|--|

Classification: -

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.

SECTION 4: First aid measures

General information Not available.

4.1. Description of 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.

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

4.3. Indication of any immediate medical attention and special treatment needed Not available.

SECTION 5: Firefighting measures

General fire hazards This product is an aqueous mixture which will not burn.

5.1. Extinguishing media

Suitable extinguishing media Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media Not available.

5.2. Special hazards arising from the substance or mixture Not available.

5.3. Advice for firefighters

Special protective equipment for firefighters Wear suitable protective equipment.

Special fire fighting procedures Not available.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Avoid inhalation of mists or aerosols.

For emergency responders Not available.

6.2. Environmental precautions Avoid release to the environment.

6.3. Methods and material 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.

6.4. Reference to other sections See Section 8 for personal protective equipment. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s) Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

| Lilly (LEG) Components | Type | Value | Form |
|--|--|-----------|-------------------|
| Insulin Glargine (CAS 160337-95-1) | STEG (15min) | 600 ug/m3 | (respirable dust) |
| | TWA (12hrs) | 120 ug/m3 | (respirable dust) |
| Biological limit values | No biological exposure limits noted for the ingredient(s). | | |
| Recommended monitoring procedures | Not available. | | |
| Derived no effect levels (DNELs) | Not available. | | |
| Predicted no effect concentrations (PNECs) | Not available. | | |
| 8.2. Exposure controls | | | |
| 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 | | | |
| General information | Not available. | | |
| Eye/face protection | Safety glasses with side-shields conforming to EN 166. | | |
| Skin protection | | | |
| - Hand protection | Protective gloves complying with EN 374. Chemical resistant gloves. | | |
| - Other | Chemical-resistant gloves and impermeable body covering to minimize skin contact. | | |
| Respiratory protection | Use a properly fitted, air purifying or air fed respirator complying with an approved standard if a risk assessment indicated that is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). | | |
| Thermal hazards | Not available. | | |
| Hygiene measures | 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. | | |
| Environmental exposure controls | Not available. | | |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

| | |
|---|-------------------|
| Physical state | Liquid. |
| Form | Liquid. |
| Colour | Colorless |
| Odour | Phenolic. |
| Odour threshold | Not available. |
| pH | 4 |
| Melting point/freezing point | Not available. |
| Initial boiling point and boiling range | Not available. |
| Flash point | Not applicable. |
| Evaporation rate | Not applicable. |
| Flammability (solid, gas) | Not applicable. |
| Upper/lower flammability or explosive limits | |
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Vapour pressure | Not applicable. |
| Vapour density | Not applicable. |
| Relative density | Not available. |
| Solubility(ies) | Soluble in water. |

| | |
|--|--|
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not applicable. |
| Explosive properties | Not explosive |
| Oxidising properties | The substance or mixture is not classified as oxidizing. |

9.2. Other information

| | |
|-------------------------|-------|
| Specific gravity | 1,004 |
|-------------------------|-------|

SECTION 10: Stability and reactivity

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|---|--|
| 10.1. Reactivity | Not water reactive. |
| 10.2. Chemical stability | Material is stable under normal conditions. |
| 10.3. Possibility of hazardous reactions | Hazardous polymerisation does not occur. |
| 10.4. Conditions to avoid | None under normal conditions. |
| 10.5. Incompatible materials | Strong oxidising agents. |
| 10.6. Hazardous decomposition products | No hazardous decomposition products are known. |

SECTION 11: Toxicological information

| | |
|---|--|
| Acute toxicity | Not expected to be active orally. |
| Routes of exposure | Inhalation. Skin contact. |
| 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 sensitiser | Due to lack of data the classification is not possible. |
| Skin sensitiser | 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. |
| Toxic to reproduction | 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. |
| Other information | Decreased blood sugar levels. Symptoms typically associated with low blood sugar may include shakiness, sweating, fatigue, hunger, irritability, confusion, and rapid heartbeat. |

SECTION 12: Ecological information

| | |
|--|--|
| 12.1. Toxicity | No data available. |
| 12.2. Persistence and degradability | No data is available on the degradability of this product. |
| 12.3. Bioaccumulative potential | No data available on bioaccumulation. |
| Partition coefficient n-octanol/water (log Kow) | Not available. |
| Bioconcentration factor (BCF) | Not available. |
| 12.4. Mobility in soil | Not available. |
| 12.5. Results of PBT and vPvB assessment | Not applicable. |
| 12.6. Other adverse effects | Not available. |

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|-------------------------------------|--|
| Residual waste | Not available. |
| Contaminated packaging | Not available. |
| EU waste code | Not available. |
| Disposal methods/information | Dispose in accordance with all applicable regulations. |

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code Not available.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, as amended

Not listed.

National regulations Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

LEG: Lilly Exposure Guideline
STEG: Short Term Exposure Guideline
TWA: Time Weighted Average

References

Not available.

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculator methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

None.

Lilly Lab Code

Health: 0
Fire: 0
Reactivity: 0

Revision information

Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients

Disclaimer

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