1. Identification

Product identifier

Erbitux®

Other means of identification

Item Code

VL7676, VL7709

Recommended use

Pharmaceutical

Recommended restrictions

None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Eli Lilly and Company

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

LSN Number

2939777

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cetuximab</td>
<td>C225, IMC-C225</td>
<td>Mixture</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

Composition comments

Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation

Call a physician if symptoms develop or persist.

Skin contact

Rinse skin with water/shower. 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 if irritation develops and persists.

Ingestion

Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed

The following adverse effects have been noted with therapeutic use of this material: Rash. Hypersensitivity reactions. Allergic reactions have been reported.

Indication of immediate medical attention and special treatment needed

General information

If you feel unwell, seek medical advice (show the label where possible).

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

Methods and materials for containment and cleaning up

Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum.

Wear appropriate protective equipment and clothing during clean-up.

Environmental precautions

Avoid release to the environment.

7. Handling and storage

Precautions for safe handling

Not available.

Conditions for safe storage, including any incompatibilities

Storage temperature: between 2 C and 8 C. Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Occupational Exposure Limit (OEL): Not established

Preliminary guidance: Control exposures to between 20 ug/m3 and 100 ug/m3 until an OEL is established.

Appropriate engineering controls

Contained handling practices preferred. If open handling is necessary, use control measures (i.e. ventilated enclosure, local exhaust ventilation) to maintain airborne levels below the 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

While monoclonal antibodies are not anticipated to be readily absorbed through the skin, wear impervious gloves and body covering (i.e. lab coat) 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.

Individual protection measures, such as personal protective equipment

This substance is a monoclonal antibody. Based on the biophysical properties and absorption characteristics of monoclonal antibodies, oral and dermal routes of exposure are not considered occupationally relevant and potential bioavailability through inhalation is minimal.

9. Physical and chemical properties

Appearance

Clear. Solution.

Physical state

Liquid.
Form: Liquid.
Color: Colorless
Odor: Not available.
Odor threshold: Not available.

pH: 5.3 - 5.7
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): Not available.
Partition coefficient (n-octanol/water): Not available.
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.

Other information:
Explosive properties: The substance or mixture is not classified as oxidizing.
Oxidizing properties: Not explosive

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 available.
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: Result in genetic toxicity assays (in vitro and in vivo): Negative
  Based on available data, the classification criteria are not met.
Carcinogenicity

No carcinogenicity data available for this product. 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 1910.1001-1050)
Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity
Experiments have shown reproductive toxicity effects on laboratory animals. Embryo-lethality. Menstrual irregularities. (Intravenous)

Based on animal models, EGFR is involved in prenatal development and may be essential for normal organogenesis, proliferation, and differentiation in the developing embryo. 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: Skin. Rash. Kidney effects. (Intravenous)
Based on available data, the classification criteria are not met.

Aspiration hazard
Not applicable.

Further information
The following adverse effects have been noted with therapeutic use of this material: Rash. Hypersensitivity reactions. Allergic reactions have been reported.

This substance is a monoclonal antibody. Based on the biophysical properties and absorption characteristics of monoclonal antibodies, oral and dermal routes of exposure are not considered occupationally relevant and potential bioavailability through inhalation is minimal.

12. Ecological information

Ecotoxicity
Not expected to be harmful to aquatic organisms.

Persistence and degradability
Not available.

Bioaccumulative potential
Not available.

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.

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 regulated.
Superfund Amendments and Reauthorization Act of 1986 (SARA)

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.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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 09-21-2015
Revision date 07-05-2017
Version # 03

Lilly Lab Code

Health: 0
Fire: 0
Reactivity: 0

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 MATERIAL 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: Physical States
First-aid measures: Eye contact
Physical & Chemical Properties: Multiple Properties
GHS: Classification