



SAFETY DATA SHEET

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

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

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

Chemical name	Common name and synonyms	CAS number	%
Cetuximab	C225 IMC-C225	Mixture	<1

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	Not available.
Indication of immediate medical attention and special treatment needed	The following adverse effects have been noted with therapeutic use of this material: Rash. Hypersensitivity reactions. Allergic reactions have been reported.
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	Avoid inhalation of mists or aerosols.
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.

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	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.

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)

Hazard categories 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

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 09-21-2015

Revision date 07-05-2017

Version # 03

Lilly Lab Code Health: 0
Fire: 0
Reactivity: 0

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For additional information contact:
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Revision information Product and Company Identification: Physical States
First-aid measures: Eye contact
Physical & Chemical Properties: Multiple Properties
GHS: Classification