



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Erbitux®</b>		
<b>Other means of identification</b>			
<b>Item Code</b>	VL7676, VL7709		
<b>LY Number</b>	LY2939777		
<b>Recommended use</b>	Pharmaceutical		
<b>Recommended restrictions</b>	None known.		
<b>Manufacturer/Importer/Supplier/Distributor information</b>			
<b>Manufacturer</b>			
<b>Company name</b>	Eli Lilly and Company		
<b>Address</b>	Lilly Corporate Center Indianapolis, IN 46285 United States		
<b>Telephone</b>	Phone:	+1-317-276-2000	
<b>E-mail</b>	lilly_msds@lilly.com		
<b>Emergency phone number</b>	CHEMTREC:	+1-800-424-9300	

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement</b>	
<b>Prevention</b>	Not available.
<b>Response</b>	Not available.
<b>Storage</b>	Not available.
<b>Disposal</b>	Not available.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	None.

## 3. Composition/information on ingredients

### Mixtures

<b>Chemical name</b>	<b>Common name and synonyms</b>	<b>CAS number</b>	<b>%</b>
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

<b>Inhalation</b>	Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	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.
<b>Ingestion</b>	Get medical attention if symptoms occur.

<b>Most important symptoms/effects, acute and delayed</b>	Not available.
<b>Indication of immediate medical attention and special treatment needed</b>	The following adverse effects have been noted with therapeutic use of this material: Rash. Hypersensitivity reactions. Allergic reactions have been reported.
<b>General information</b>	If you feel unwell, seek medical advice (show the label where possible).

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	Not available.
<b>Specific hazards arising from the chemical</b>	Not applicable.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>General fire hazards</b>	This product is an aqueous mixture which will not burn.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Avoid inhalation of mists or aerosols.
<b>Methods and materials for containment and cleaning up</b>	Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum. Wear appropriate protective equipment and clothing during clean-up.
<b>Environmental precautions</b>	Avoid release to the environment.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Not available.
<b>Conditions for safe storage, including any incompatibilities</b>	Storage temperature: between 2 C and 8 C. Keep container tightly closed in a dry and well-ventilated place.

## 8. Exposure controls/personal protection

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	Occupational Exposure Limit (OEL): Not established Preliminary guidance: Control exposures to between 20 ug/m3 and 100 ug/m3 until an OEL is established.
<b>Appropriate engineering controls</b>	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).
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemical resistant gloves.
<b>Other</b>	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.
<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	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

<b>Appearance</b>	Clear. Solution.
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.

<b>Color</b>	Colorless
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	5.3 - 5.7
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	The substance or mixture is not classified as oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	Not water reactive.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	None under normal conditions.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on toxicological effects

<b>Acute toxicity</b>	Not available.
<b>Skin corrosion/irritation</b>	Due to lack of data the classification is not possible.
<b>Serious eye damage/eye irritation</b>	Due to lack of data the classification is not possible.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.
<b>Skin sensitization</b>	Due to lack of data the classification is not possible.
<b>Germ cell mutagenicity</b>	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 1910.1001-1052)**

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.

### 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.

**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** 02-19-2019

**Version #** 04

**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