



SAFETY DATA SHEET

1. Identification

Product identifier Portrazza™
Other means of identification
Item Code CT9735, ZD0090, VL7716
Synonyms LY3012211
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

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	%
Necitumumab	Immunoglobulin G1, anti-(human epidermal growth factor receptor) (human monoclonal IMC-11F8 γ 1-chain), disulfide with human monoclonal IMC-11F8 κ -chain, dimer	906805-06-9	1.6

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 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 This substance is a monoclonal antibody. Based on the biophysical properties and absorption characteristics of monoclonal antibodies, this substance/preparation is considered unlikely to produce health effects through relevant routes of occupational exposures.

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 No specific precautions.

7. Handling and storage

Precautions for safe handling Avoid breathing mist or vapor. See Section 8 of the SDS for Personal Protective Equipment.

Conditions for safe storage, including any incompatibilities Storage temperature: between 2 and 8 C. Do not allow material to freeze. Do not shake material. Protect from light.

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG)

Components

	Type	Value
Necitumumab (CAS 906805-06-9)	TWA (12hrs)	110 ug/m3
	TWA (8hrs)	165 ug/m3

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

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. (drug substance)

9. Physical and chemical properties

Appearance clear to slightly opalescent.

Physical state	Liquid.
Form	Liquid.
Color	colorless to light yellow.
Odor	Not available.
Odor threshold	Not available.
pH	6
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)	This product is a nonflammable aqueous solution.
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
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.
VOC (Weight %)	0.03 % estimated

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 applicable.
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 This substance is a monoclonal antibody. It does not possess mutagenic potential. Mutagenicity testing has not been conducted. (drug substance)
Based on available data, the classification criteria are not met.

Carcinogenicity Not listed by IARC, NTP, ACGIH or OSHA. (drug substance)
Due to lack of data the classification is not possible.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicity Reproductive studies have not been conducted. Based on animal models, EGFR is involved in prenatal development and may be essential for normal organogenesis, proliferation, and differentiation in the developing embryo. (drug substance) Based on the nature of this substance and the known health effects of the components, this preparation is considered unlikely to produce health effects through relevant routes of occupational exposures.
Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure Not applicable.

Specific target organ toxicity - repeated exposure Monkeys were administered once-weekly IV doses for 26 weeks (6, 19, or 60 mg/kg/dose). Adverse compound-related effects included gross and microscopic skin lesions which were reported at all dose levels. A single high-dose monkey developed disseminated intravascular coagulation which resulted in mortality. The cause of this finding has not been established. (drug substance)
Based on available data, the classification criteria are not met.

Aspiration hazard Not applicable.

Further information 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. (drug substance)
Effects reported with therapeutic administration: Dermatitis. Rash. Hypersensitivity reactions. Conjunctivitis. (Intravenous)

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 listed.

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.
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US state regulations**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

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	11-24-2015
Revision date	12-03-2015
Version #	02
Lilly Lab Code	Health: 0 Fire: 0 Reactivity: 0

Disclaimer

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Revision Information

Toxicological information: Reproductivity