SAFETY DATA SHEET

1. Identification

Product identifier **Portrazza™**

Other means of identification

Item Code CT9735, ZD0090, VL7716

LY Number LY3012211

Recommended use Pharmaceutical

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Eli Lilly and Company

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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 γ1-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

Physical state Liquid.

Form	Liquid.
Color	Colourless 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 an aqueous mixture which will not burn.
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	No oxidizing properties.

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 listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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.

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 11-24-2015

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Version # 03

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 MERCHANT ABILITY 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.

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