Lilly

SAFETY DATA SHEET

1. Identification

Product identifier Cyramza™

Other means of identification

Item CodeVL7678, VL7669Recommended usePharmaceuticalRecommended restrictionsNone known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name
Address
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

LY Number LY3009806 **LSN Number** 3009806

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	%
Ramucirumab		NA	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 Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Get medical attention if symptoms occur.

Material name: Cyramza™ sds us

Most important

symptoms/effects, acute and

delayed

Not available.

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

Specific hazards arising from

the chemical

This product is an aqueous mixture which will not burn.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Not available.

Not available.

Methods and materials for containment and cleaning up Prevent runoff from entering drains, sewers, or streams. Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum. See Section 8 of the SDS for Personal

Protective Equipment.

No specific precautions. **Environmental precautions**

7. Handling and storage

Precautions for safe handling

Not available.

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

Protect from light.

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG)

Components	Туре	Value	
Ramucirumab	TWA (12hrs)	110 ug/m3	
	TWA (8hrs)	165 ug/m3	

Biological limit values No biological exposure limits noted for the ingredient(s). **Exposure guidelines** Occupational Exposure Limit (OEL): Not 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

Safety glasses with side shields recommended. If splash potential or dusty operations, wear Eye/face protection

goggles/faceshield.

Skin protection

Chemical resistant gloves. **Hand protection**

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.

Not required under normal conditions for liquid handling activities. If handling powder forms, Respiratory protection

consider appropriate respiratory protection to maintain exposure levels below occupational

exposure level (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 to opalescent.

Material name: Cyramza™ SDS US **Physical state** Liquid.

Form Aqueous solution. Color Colorless to light yellow.

Odor Not available. **Odor threshold** Not available. Not available. Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

Not available. Flash point **Evaporation rate** Not available. Not applicable. Flammability (solid, gas) Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available. Not available. Explosive limit - upper (%) Not available. Vapor pressure Vapor density Not available. Relative density Not available.

Solubility(ies)

Not available. Solubility (water) **Partition coefficient** Not available.

(n-octanol/water)

Auto-ignition temperature Not available. **Decomposition temperature** Not available. **Viscosity** Not available.

Other information

Not explosive **Explosive properties**

Oxidizing properties No oxidizing properties.

pH in aqueous solution Neutral

10. Stability and reactivity

Reactivity Not water reactive.

Material is stable under normal conditions. **Chemical stability** Possibility of hazardous Hazardous polymerization does not occur.

reactions

None under normal conditions. Conditions to avoid

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Not applicable. **Acute toxicity**

Due to lack of data the classification is not possible. Skin corrosion/irritation Serious eye damage/eye Due to lack of data the classification is not possible.

irritation

Respiratory or skin sensitization

Due to lack of data the classification is not possible. Respiratory sensitization Skin sensitization Due to lack of data the classification is not possible.

Material name: Cyramza™

This substance is a monoclonal antibody. It does not possess mutagenic potential. Mutagenicity Germ cell mutagenicity

testing has not been conducted.

Due to lack of data the classification is not possible.

No test data available. Not listed by IARC, NTP, ACGIH or OSHA. Carcinogenicity

Due to lack of data the classification is not possible.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed

Reproductive toxicity No test data available.

> VEGF is a critical mediator of angiogenesis that occurs across several stages of the female reproductive cycle, pregnancy, and embryo-fetal development. Interference of VEGF signaling through the use of transgenic models (for example, knockout mice), nonproprietary antibodies against VEGF or its receptors against VEGFR-2 have been shown to block angiogenesis and functioning or development of tissues critical for mammalian reproduction and development.

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: Kidney effects. (glomerulonephritis) Ovarian

changes. (follicular mineralization) (drug substance) (Intravenous)

Based on available data, the classification criteria are not met.

Aspiration hazard Not applicable.

Further information Effects reported with therapeutic administration: Increased risk of hemorrhage, serious arterial

thromboembolic events (ATEs) including myocardial infaction, cardiac arrest, cerebrovascular

accident, cerebral ischemia, increased incidence of severe hypertension.

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.

Not available. Persistence and degradability Bioaccumulative potential Not available. Mobility in soil Not available. Not available. Other adverse effects

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 Not available. Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication **US** federal regulations

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)

SARA 304 Emergency release notification

Not regulated.

Material name: Cyramza™ SDS US

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

Not regulated.

(SDWA)

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
 11-20-2014

 Revision date
 08-25-2015

Version # 03

Lilly Lab Code Health: 0

Fire: 0 Reactivity: 0

List of abbreviations

LEG: Lilly Exposure Guideline TWA: Time Weighted Average

Material name: Cyramza™ sps us

5/6

4820 Version #: 03 Revision date: 08-25-2015 Issue date: 11-20-2014

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 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.

For additional information contact: Eli Lilly and Company Hazard Communication

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Revision Information

Composition / Information on Ingredients: Disclosure Overrides

Physical & Chemical Properties: Multiple Properties Physical and chemical properties: Appearance Physical and chemical properties: Form Toxicological information: Reproductivity Regulatory information: US federal regulations

Other information, including date of preparation or last revision: List of abbreviations

Material name: Cyramza™ sps us