



SAFETY DATA SHEET

1. Identification

Product identifier	Emgality™
Other means of identification	
Item Code	703431, 702650, 701220, CT9582, 703168, 703167, 703166, 701324, PS3115, PS2377, PS1436, PS1424, 703179, 703178, 703177, 703175, 703174, PS2234, CT9739, CT9740, CT9741
LY Number	LY2951742
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_sds@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.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Galcanezumab		N/A	4 - 12

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.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

5. Fire-fighting measures

Suitable extinguishing media Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media None known.

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 No specific recommendations.

Conditions for safe storage, including any incompatibilities Keep refrigerated Storage temperature: between 2 and 8 C.

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG)

Components

Type

Value

Galcanezumab	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 Not required under normal conditions for liquid handling activities. If handling powder forms, consider appropriate respiratory protection to maintain exposure levels below occupational exposure level (OEL).

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

Physical state Liquid.

Form Aqueous Solution

Color	Clear to cloudy.
Odor	Odorless
Odor threshold	Not available.
pH	Neutral
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	
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	Not 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	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
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	Mutagenicity testing has not been conducted. This substance is a monoclonal antibody. It does not possess mutagenic potential. (Galcanezumab) Based on available data, the classification criteria are not met.
Carcinogenicity	Not listed by IARC, NTP, ACGIH or OSHA. Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity	Animal studies did not report any adverse effects on reproductive tissues, fertility, or embryo/fetal development. (subcutaneous) (Galcanezumab) Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	No significant adverse effects reported. (subcutaneous) (Galcanezumab) 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.

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.
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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 1910.1001-1053)

Not listed.

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.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

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	09-19-2018
Revision date	12-23-2021
Version #	11

List of abbreviations

ACGIH: American Conference of Governmental Industrial Hygienists.
 DOT: Department of Transportation (49 CFR 172.101).
 EC50: Effective Concentration 50%.
 HEPA: High Efficiency Particulate Air.
 IARC: International Agency for Research on Cancer.
 IATA: International Air Transport Association.
 IMDG Code: International Maritime Dangerous Goods Code.
 LC50: Lethal Concentration 50%.
 LD50: Lethal Dose 50%.
 LEG: Lilly Exposure Guideline.
 NIOSH: National Institute for Occupational Safety & Health.
 NTP: National Toxicology Program.
 OSHA: Occupational Safety & Health Administration.
 PEL: Permissible Exposure Limit.
 RID: Regulations concerning the international carriage of dangerous goods by rail (Règlement International concernant le transport de marchandises dangereuses par chemin de fer).
 STEL: Short-Term Exposure Limit.
 TLV: Threshold Limit Value.

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:
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 Hazard Communication
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Revision information

Product and Company Identification: Product Codes
 First-aid measures: Indication of immediate medical attention and special treatment needed
 Exposure controls/personal protection: Occupational exposure limits
 Physical and chemical properties: Oxidizing properties
 Regulatory information: California Proposition 65