# SAFETY DATA SHEET



### 1. Identification

**Product identifier LARTRUVO™** 

Other means of identification

**Item Code** VL7190, CT2059, VL8926

LY3012207 LY Number Recommended use Pharmaceutical **Recommended restrictions** None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Eli Lilly and Company Company name Lilly Corporate Center **Address** Indianapolis, IN 46285

**United States** 

Telephone Phone: +1-317-276-2000

E-mail lilly msds@lilly.com

CHEMTREC: +1-800-424-9300 **Emergency phone number** 

2. Hazard(s) identification

Not classified. Physical hazards Not classified. **Health hazards OSHA** defined hazards Not classified.

Label elements

None. Hazard symbol Signal word None.

The mixture does not meet the criteria for classification. Hazard statement

**Precautionary statement** 

Prevention Not available. Not available. Response Storage Not available. Not available. Disposal

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	%
Olaratumab		1024603-93-7	1

Remaining components of this product are non-hazardous and/or are present at concentrations Composition comments

below reportable levels.

4. First-aid measures

Inhalation Call a physician if symptoms develop or persist.

Rinse skin with water/shower. Get medical attention if irritation develops and persists. Skin contact

Rinse with water. Get medical attention if irritation develops and persists. Eye contact

Get medical attention if symptoms occur. Ingestion

Most important

This mixture contains a monoclonal antibody. Based on the biophysical properties and absorption characteristics of monoclonal antibodies, this substance/preparation is considered unlikely to symptoms/effects, acute and

produce health effects through relevant routes of occupational exposures. delayed

SDS US 1/5 5514 Version #: 04 Revision date: 02-06-2019 Issue date: 11-03-2016

Material name: LARTRUVO™

### 5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing

Not available.

media

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 agueous mixture which will not burn.

Use extinguishing media appropriate for surrounding fire.

#### 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

Not available.

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

### 8. Exposure controls/personal protection

#### Occupational exposure limits

Lilly (LEG) Components	Туре	Value	
Olaratumab (CAS 1024603-93-7)	TWA (12hrs)	35 ug/m3	
	TWA (8hrs)	50 ug/m3	

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

Appropriate engineering

controls

Open handling is not recommended. Use appropriate control measure (i.e. fume hood, ventilated enclosure, local exhaust ventilation) to maintain airborne levels below 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.

If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an Respiratory protection

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 mixture contains 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

Clear to slightly opalescent liquid. **Appearance** 

Physical state Liquid. Not available. **Form** 

Color Colorless to Light yellow

Odor Not available.

Material name: LARTRUVO™ 2/5

Not available. Odor threshold

5.3 - 5.7 Ha

Melting point/freezing point

Initial boiling point and boiling

Not available. Not available.

range

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

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

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

Solubility(ies)

Soluble Solubility (water)

Not available. Partition coefficient

(n-octanol/water)

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

Other information

Not explosive. **Explosive properties** 

**Oxidizing properties** The substance or mixture is not classified as oxidizing.

# 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

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

Based on available data, the classification criteria are not met. **Acute toxicity** 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. Due to lack of data the classification is not possible. Skin sensitization

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

testing has not been conducted.

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

Not listed by IARC, NTP, ACGIH or OSHA. Carcinogenicity

Due to lack of data the classification is not possible.

Material name: LARTRUVO™ SDS US

#### 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 Studies of PDGFs and PDGFRs in animal development have indicated that disruption of PDGFR

alpha signaling may impair gastrulation and the development of the cardiac and cranial neural

crest, gonads, lung, intestine, skin, central nervous system, and skeleton.

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

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

Aspiration hazard Not applicable.

**Further information**This mixture contains a monoclonal antibody. Based on the biophysical properties and absorption

characteristics of monoclonal antibodies, oral and dermal routes of exposure are not considered

No adverse effects reported in animals administered 75 mg/kg intravenously weekly for 39 weeks.

occupationally relevant and potential bioavailability through inhalation is minimal.

### 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Persistence and degradability
Bioaccumulative potential
Mobility in soil

Other adverse effects

Not available.
Not available.
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 Not available.

Annex II of MARPOL 73/78 and

the IBC Code

# 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.

Material name: LARTRUVO™

#### 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 regionInventory nameOn inventory (yes/no)\*CanadaDomestic Substances List (DSL)NoCanadaNon-Domestic Substances List (NDSL)NoUnited States & Puerto RicoToxic Substances Control Act (TSCA) InventoryNo

# 16. Other information, including date of preparation or last revision

 Issue date
 11-03-2016

 Revision date
 02-06-2019

Version # 04

**List of abbreviations** LEG: Lilly Exposure Guideline.

TWA: Time Weighted Average

Disclaimer

This document provides available information relevant to the handling of the experimental material identified above. Some of the information contained herein is preliminary, and some sections may contain opinions based on available scientific information. All of the information is offered with the good faith belief that it is accurate, but this safety data sheet does not constitute a warranty of any kind, express or implied. This document has been made available so that proper protective measures can be taken by persons who may be exposed to the material during pre-market research and development activities. In the event of any adverse incident associated with this material, the safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel.

For additional information contact:

Eli Lilly and Company Hazard Communication +1-317-651-9533

Material name: LARTRUVO™ SDS US

<sup>\*</sup>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).