Lilly

SAFETY DATA SHEET

1. Identification

Product identifier Taltz®

Other means of identification

Item Code PS1445, PS7724, 520047, 517421, ZD1445, ZD7724, PS1439, CT9557

Synonyms LY2439821 formulation

Recommended use Pharmaceutical **Recommended restrictions** None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

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

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 None known.

classified (HNOC)

Supplemental information None.

3. Composition/information on ingredients

Mixtures

 Chemical name
 Common name and synonyms
 CAS number
 %

 Ixekizumab
 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.

Material name: Taltz® sps us

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

Unsuitable extinguishing

media

Use fire-extinguishing media appropriate for surrounding materials.

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.

Not available.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Methods and materials for

containment and cleaning up

Avoid inhalation of mists or aerosols.

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.

Environmental precautions No specific precautions.

7. Handling and storage

Precautions for safe handling

Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Occupational exposure limits

cupational exposure illilits | Lilly (LEG)

Components	Туре	Value	
Ixekizumab	TWA (12hrs)	250 ug/m3	
	TWA (8hrs)	380 ug/m3	

Biological limit values

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

Exposure guidelines

Health Based Excursion Limit: Maintain Full Shift TWA

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).

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

Material name: Taltz® sps us

Physical state Liquid.
Form Liquid.
Color Colorless.
Odor Odorless
Odor threshold Not available.

pH 5.7

Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

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

Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Explosive properties Not explosive

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

10. Stability and reactivity

Reactivity Not water reactive.

Chemical stability Material is stable under normal conditions.

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

Acute toxicity

Due to lack of data the classification is not possible.

Skin corrosion/irritation

Due to lack of data the classification is not possible.

Serious eye damage/eye

Due to lack of data the classification is not possible.

irritation

Respiratory or skin sensitization

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

Material name: Taltz® SDS US

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

testing has not been conducted. (drug substance)

Not listed by IARC, NTP, ACGIH or OSHA. (drug substance) Carcinogenicity

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)

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicity Animal studies did not report any adverse effects on reproductive tissues, fertility ,or embryo/fetal

development. (Weekly dosing) (drug substance)

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

Except for injection site reactions, no treatment-related adverse effects have been reported in monkeys administered once-weekly subcutaneous doses for up to 39 weeks. (drug substance) Based on available data, the classification criteria are not met.

Aspiration hazard Not applicable.

This substance is a monoclonal antibody. Based on the biophysical properties and absorption **Further information**

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

occupationally relevant and potential bioavailability through inhalation is minimal. (drug

substance)

12. Ecological information

12.1. Toxicity Not expected to be harmful to aquatic organisms. Not available.

12.2. Persistence and

degradability

12.3. Bioaccumulative potential Not available.

Partition coefficient

Not available.

n-octanol/water (log Kow)

Not available. Bioconcentration factor (BCF) 12.4. Mobility in soil Not available. 12.6. 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 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.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Material name: Taltz® SDS US

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

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

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

Issue date 03-23-2016

Version # 01

Lilly Lab Code Health: 0 Fire: 0

Fire: 0 Reactivity: 0

List of abbreviations

LEG: Lilly Exposure Guideline TWA: Time Weighted Average

Material name: Taltz® sps us

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 +1-317-651-9533

Revision Information

Product and Company Identification: Product Codes Physical and chemical properties: Flammability (solid, gas)

Toxicological information: Mutagenicity

Other information, including date of preparation or last revision: Disclaimer

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

Material name: Taltz® sps us