



SAFETY DATA SHEET

1. Identification

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|---|--|
| Product identifier | Mounjaro™ |
| Other means of identification | |
| Item Code | PS1462, PS3325, PS3516, PS3681, PS3837, PS4170, PS4043, 703550, 703551, 703552, 703553, 703554, 703555, 703561, 703562, 703563, 703570, 703571, 703572, PS1457, PS1460, PS1471, PS1484, PS1495, PS1506, 702212, 702211, 702210, 702186, 702187, 702188, 702220, 702216, 702215, 702214, 702213, 702200, 702197, 702196, 702195, 702194, 702193, 702192, 701410, 701626, 701053, 701622, 701052, 701624, 701599, 701598, CT9752, CT9751, CT9750, CT9749, 701580, 701327, CT2085, 701010, CT9579, 700991, CT9578 |
| Synonyms | Tirzepatide Injection |
| 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 substance 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 | % |
|----------------------|---------------------------------|-------------------|----------|
| Tirzepatide | | 2023788-19-2 | 1 - 3 |

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

4. First-aid measures

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| Inhalation | Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately. |
| Skin contact | Wash off immediately with plenty of water for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse. |
| Eye contact | Immediately flush eye(s) with plenty of water. Get medical attention. |

Ingestion Consult a physician.

Most important symptoms/effects, acute and delayed May cause nausea, decreased appetite, diarrhea, and vomiting. May cause decrease in blood sugar. Symptoms typically associated with low blood sugar may include shakiness, sweating, fatigue, hunger, irritability, confusion, and rapid heartbeat.

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

5. Fire-fighting measures

Suitable extinguishing media Carbon dioxide, dry chemical or water.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical Hazardous decomposition products formed under fire conditions.

Special protective equipment and precautions for firefighters Wear self-contained breathing apparatus and protective clothing.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.

Methods and materials for containment and cleaning up Stop the flow of material, if this is without risk. Use absorbent/adsorbent material to solidify liquids. Clean surface thoroughly to remove residual contamination.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. See Section 8 of the SDS for Personal Protective Equipment.

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

Lilly (LEG)

Components

Tirzepatide (CAS
2023788-19-2)

Type

TWA (12hrs)

Value

60 ug/m3

TWA (8hrs)

90 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 Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.

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

Chemical-resistant gloves and impermeable body covering 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.

General hygiene considerations Tirzepatide is an active pharmaceutical ingredient with a therapeutic dose in humans at or below 1 mg/day.

9. Physical and chemical properties

Appearance

Physical state

Liquid.

Form

Aqueous Solution

Color

Clear. Colorless.

Odor

Odorless

| | |
|--|-------------------------------------|
| Odor threshold | Not available. |
| pH | 6.5 - 7.5 |
| 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) | No data available for this product. |

Upper/lower flammability or explosive limits

| | |
|------------------------------------|----------------|
| Explosive limit - lower (%) | Not available. |
| Explosive limit - upper (%) | Not available. |

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|-------------------------|----------------|
| Vapor pressure | Not available. |
| Vapor density | Not available. |
| Relative density | Not available. |

Solubility(ies)

| | |
|---------------------------|----------|
| Solubility (water) | Soluble. |
|---------------------------|----------|

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|--|----------------|
| Partition coefficient (n-octanol/water) | Not available. |
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|----------------------------------|----------------|
| Auto-ignition temperature | Not available. |
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|----------------------------------|----------------|
| Decomposition temperature | Not available. |
|----------------------------------|----------------|

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|------------------|----------------|
| Viscosity | Not available. |
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Other information

| | |
|-----------------------------|----------------|
| Explosive properties | Not explosive. |
| Oxidizing properties | Not oxidizing. |

10. Stability and reactivity

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|-------------------|---------------------|
| Reactivity | Not water reactive. |
|-------------------|---------------------|

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|---------------------------|---|
| Chemical stability | Material is stable under normal conditions. |
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| Possibility of hazardous reactions | Hazardous polymerization does not occur. |
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| Conditions to avoid | Contact with incompatible materials. |
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|-------------------------------|------------------------------|
| Incompatible materials | Strong oxidizing substances. |
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| Hazardous decomposition products | Hazardous decomposition products formed under fire conditions. |
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11. Toxicological information

Information on toxicological effects

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| Acute toxicity | Not expected to be active orally. |
|-----------------------|-----------------------------------|

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|----------------------------------|---|
| 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. |
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|-------------------------------|--|
| Germ cell mutagenicity | Negative In vivo micronucleus test: (Tirzepatide) Based on available data, the classification criteria are not met. |
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|------------------------|---|
| Carcinogenicity | Not listed by IARC, NTP, ACGIH or OSHA. In a 2-year carcinogenicity study in rats, Tirzepatide caused statistically significant dose-related increases in the incidence of thyroid C-cell tumors (adenomas and carcinomas combined) following twice weekly subcutaneous administration. The human relevance of these findings is currently unknown. Thyroid C-cell changes were not reported in monkeys or in a 6-month carcinogenicity study in transgenic mice. 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 testing did not show any effects on fertility. Developmental effects have been reported at doses toxic to the mother. (Tirzepatide) Based on available data, the classification criteria are not met. |
| Specific target organ toxicity - single exposure | No target organ toxicity identified through animal studies. (Tirzepatide) Based on available data, the classification criteria are not met. |
| Specific target organ toxicity - repeated exposure | No target organ toxicity identified through animal studies. (Tirzepatide) Based on available data, the classification criteria are not met. |
| Aspiration hazard | Not applicable. |
| Further information | May cause nausea, decreased appetite, diarrhea, and vomiting. May cause decrease in blood sugar. Symptoms typically associated with low blood sugar may include shakiness, sweating, fatigue, hunger, irritability, confusion, and rapid heartbeat. |

12. Ecological information

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|--------------------------------------|---|
| Ecotoxicity | Due to lack of data the classification is not possible. |
| Persistence and degradability | Readily biodegradable. (Tirzepatide) |
| Bioaccumulative potential | No data available on bioaccumulation. |
| Mobility in soil | Not available. |
| Other adverse effects | Not available. |

13. Disposal considerations

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|------------------------------|--|
| 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. |
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15. Regulatory information

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| 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. |
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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 05-24-2022

Version # 01

List of abbreviations

ACGIH: American Conference of Governmental Industrial Hygienists.
DOT: Department of Transportation (49 CFR 172.101).
IATA: International Air Transport Association.
IARC: International Agency for Research on Cancer.
IMDG Code: International Maritime Dangerous Goods Code.
LEG: Lilly Exposure Guideline.
NTP: National Toxicology Program.
OSHA: Occupational Safety & Health Administration.
PEL: Permissible Exposure Limit.
STEG: Short Term Exposure Guideline.
TWA: Time Weighted Average 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.

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Revision information

Product and Company Identification: Alternate Trade Names