SAFETY DATA SHEET

1. Identification

Product identifier Olumiant®

Other means of identification

Item Code
701834, 701833, 701832, 701831, 701830, ZD4732, 701014, 521075, 516119, 701012, 521076, 515931, TA4732, 703144, ZD1520, ZD4182, ZD4479, TA4479, TA4182, ZD0088, CT2026, CT5168, CT5166, ZD5147, ZD5149

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
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
Reproductive toxicity Category 1B
Specific target organ toxicity, repeated exposure Category 2 (bone marrow, lymphoid system)

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement
H360 May damage fertility or the unborn child.
H373 May cause damage to organs (Bone marrow, lymphoid system) through prolonged or repeated exposure.

Precautionary statement

Prevention
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P281 Use personal protective equipment as required.

Response
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage Not available.

Disposal Not available.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures
<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baricitinib</td>
<td>IUPAC Name: (1-(\text{Ethylsulfonyl})-3-[4-(7H-\text{pyrrolo}[2,3-D][\text{pyrimidin-4-YL}]-1H-\text{pyrazol-1-YL})\text{azetidin-3-YL})\text{acetonitrile})</td>
<td>1187594-09-7</td>
<td>0.2 - 2</td>
</tr>
</tbody>
</table>

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

**4. First-aid measures**

**Inhalation**
Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.

**Skin contact**
Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.

**Eye contact**
In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

**Ingestion**
Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.

**Most important symptoms/effects, acute and delayed**
May cause reproductive effects. May cause bone marrow effects. May cause immune system effects.

**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**
The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.
Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

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

**7. Handling and storage**

**Precautions for safe handling**
Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. Avoid release to the environment.

**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**

<table>
<thead>
<tr>
<th>Lilly (LEG) Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baricitinib (CAS 1187594-09-7)</td>
<td>TWA (12hrs)</td>
<td>5 ug/m³</td>
</tr>
<tr>
<td></td>
<td>TWA (8hrs)</td>
<td>8 ug/m³</td>
</tr>
</tbody>
</table>

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

**Exposure guidelines**
Health Based Excursion Limit: Maintain Full Shift TWA
The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, isolator (i.e. glove bag/glove box) and/or closed transfers 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**
  - 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.

- **Respiratory protection**
  - Not available.

- **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.

### 9. Physical and chemical properties

**Appearance**

- **Physical state**
  - Solid.
- **Form**
  - Tablet.
- **Color**
  - Pink.

**Odor**

- Odorless

**Odor threshold**

- Not available.

**pH**

- Not available.

**Melting point/freezing point**

- 413.6 °F (212 °C) (active ingredient)

**Initial boiling point and boiling range**

- Not available.

**Flash point**

- Not available.

**Evaporation rate**

- Not available.

**Flammability (solid, gas)**

- Not a flammable solid

**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)**
  - 18.1 mg/l @pH 7 (active ingredient)
  - 19.6 mg/l @pH 9 (active ingredient)
  - 21.4 mg/l @pH 5 (active ingredient)

**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**
  - No oxidizing properties.
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 known.
Incompatible materials Strong oxidizing substances.
Hazardous decomposition products Hazardous decomposition products formed under fire conditions.

11. Toxicological information
Information on toxicological effects
Acute toxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baricitinib (CAS 1187594-09-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD Rabbit</td>
<td>&gt; 1000 mg/kg (phosphate salt)</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD Rat</td>
<td>&gt; 600 mg/kg (phosphate salt)</td>
<td></td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Rabbit: No skin irritation. (Active ingredient(s))</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Bovine Corneal Opacity and Permeability assay: No eye irritation. (active ingredient)</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>Respiratory or skin sensitization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Result in genetic toxicity assays (in vitro and in vivo): Negative (Active ingredient(s))</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not listed by IARC, NTP, ACGIH or OSHA. Animal testing did not show any carcinogenic effects. (Active ingredient(s))</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>IARC Monographs. Overall Evaluation of Carcinogenicity</td>
<td>Not listed.</td>
<td></td>
</tr>
<tr>
<td>US. National Toxicology Program (NTP) Report on Carcinogens</td>
<td>Not listed.</td>
<td></td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Reproductive studies have been conducted in rats and rabbits. In a rat embryo-fetal development study, skeletal malformations including bent limbs and rib anomalies and an increased incidence of skeletal development variations occurred in fetuses at the mid- and high-doses (10 and 40 mg/kg/day respectively). In a fertility and embryonic development study in rats, decreased male fertility and copulation indices occurred at the 50 mg/kg dose. Decreased female fertility and conception indices, decreased numbers of corpora lutea and implantation sites, increased pre-implantation loss, and /or adverse effects on intrauterine survival of the embryos occurred at dose levels of 25 and 100 mg/kg. In a rat pre-postnatal study, lower pre-weaning pup body weights and body weight gains were reported in the F1 generation. (Active ingredient(s))</td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity - single exposure</td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>The major cell types affected by baricitinib-related JAK inhibition in the nonclinical safety studies were lymphocytes and eosinophils. Associated with these changes were generalized lymphoid depletion and bone marrow hypocellularity. These immunosuppressive effects generally resolved by the end of the recovery phases. Decreases in lymphocytes and eosinophils in dogs were associated with clinical manifestations of immunosuppression including demodectic mange and bacterial, protozoal, and/or yeast infections. In addition to immunosuppression, evidence of renal tubular toxicity due to crystal formation and exacerbation of cardiomyopathy was seen in rats given high doses of baricitinib for 6 months. (active ingredient)</td>
<td></td>
</tr>
</tbody>
</table>
12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baricitinib (CAS 1187594-09-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50</td>
<td>Algae (Pseudokirchneriella subcapitata)</td>
<td>&gt; 23 mg/l, 72 Hours</td>
</tr>
<tr>
<td>NOEC</td>
<td>Algae (Pseudokirchneriella subcapitata)</td>
<td>3.1 mg/l, 72 Hours</td>
</tr>
<tr>
<td><strong>Aquatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50</td>
<td>Daphnia magna</td>
<td>22 mg/l, 48 Hours</td>
</tr>
<tr>
<td>LC50</td>
<td>Fathead minnow (Pimephales promelas)</td>
<td>&gt; 18 mg/l, 96 Hours</td>
</tr>
<tr>
<td>NOEC</td>
<td>Sewage microorganisms</td>
<td>&gt; 1000 mg/kg, 3 Hours</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOEC</td>
<td>Daphnia magna</td>
<td>4.2 mg/l, 21 days</td>
</tr>
<tr>
<td>NOEC</td>
<td>Daphnia magna</td>
<td>2.1 mg/l, 21 days</td>
</tr>
<tr>
<td>LOEC</td>
<td>Fathead minnow (Pimephales promelas)</td>
<td>1.3 mg/l, 32 days</td>
</tr>
<tr>
<td>NOEC</td>
<td>Fathead minnow (Pimephales promelas)</td>
<td>0.6 mg/l, 32 days</td>
</tr>
<tr>
<td><strong>Terrestrial</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOEC</td>
<td>Midge (Chironomus riparius)</td>
<td>&gt; 706 mg/kg, 28 days</td>
</tr>
<tr>
<td>NOEC</td>
<td>Midge (Chironomus riparius)</td>
<td>706 mg/kg, 28 days</td>
</tr>
</tbody>
</table>

A LAEG is the maximum allowable concentration at the point of application that is expected to result in no appreciable risk to populations of aquatic and terrestrial organisms, or to human health.

**LILLY AQUATIC EXPOSURE GUIDELINES:**

**Baricitinib**

- Acute LAEG (at the edge of the acute mixing zone): 846 µg/l
- Chronic LAEG (at the edge of the chronic mixing zone): 8.3 µg/l
- Drinking water LAEG (at the point where surface water is taken for drinking water): 0.93 µg/l

**Persistence and degradability**

No data is available on the degradability of this product.

**Bioaccumulative potential**

No data available on bioaccumulation.

**Partition coefficient n-octanol / water (log Kow)**

- Baricitinib: 1.38, @ pH 5, 25C (shake-flask)
- Baricitinib: 1.42, @ pH 7, 25C (shake-flask)
- Baricitinib: 1.5, @ pH 9, 25C (shake-flask)

**Mobility in soil**

**Adsorption**

- Soil/sediment sorption - log Koc: 2.71 - 3.02, 2 sludges
- Soil/sediment sorption - log Koc: 4.25 - 4.58, 3 soils

**Other adverse effects**

Not available.

13. Disposal considerations

**Disposal instructions**

Dispose of contents/container in accordance with local/regional/national/international 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 Annex II of MARPOL 73/78 and the IBC Code

15. Regulatory information

US federal regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

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)
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

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 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.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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 05-23-2018
Revision date 12-19-2018
Version # 05

List of abbreviations
LEG: Lilly Exposure Guideline.
TWA: Time Weighted Average
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:
Eli Lilly and Company
Hazard Communication
+1-317-651-9533