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

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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

Chemical name	Common name and synonyms	CAS number	%
Baricitinib	IUPAC Name: {1-(Ethylsulfonyl)-3-[4-(7H-pyrrolo[2,3-D][pyrimidin-4-YL)-1H-pyrazol-1-YL]azetidin-3-YL}acetonitrile	1187594-09-7	0.2 - 2

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

Lilly (LEG)

Components	Type	Value
Baricitinib (CAS 1187594-09-7)	TWA (12hrs)	5 ug/m3
	TWA (8hrs)	8 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	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.
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

Components	Species	Test Results
Baricitinib (CAS 1187594-09-7)		
Acute		
Dermal		
LD	Rabbit	> 1000 mg/kg (phosphate salt)
Oral		
LD	Rat	> 600 mg/kg (phosphate salt)

Skin corrosion/irritation	Rabbit: No skin irritation. (Active ingredient(s)) Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Bovine Corneal Opacity and Permeability assay: No eye irritation. (active ingredient) 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	Result in genetic toxicity assays (in vitro and in vivo): Negative (Active ingredient(s)) Based on available data, the classification criteria are not met.
Carcinogenicity	Not listed by IARC, NTP, ACGIH or OSHA. Animal testing did not show any carcinogenic effects. (Active ingredient(s)) Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity	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))
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	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)

Aspiration hazard Not applicable.

12. Ecological information

Ecotoxicity

Components		Species	Test Results
Baricitinib (CAS 1187594-09-7)			
Acute			
	EC50	Algae (Pseudokirchneriella subcapitata)	> 23 mg/l, 72 Hours
	NOEC	Algae (Pseudokirchneriella subcapitata)	3.1 mg/l, 72 Hours
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	22 mg/l, 48 Hours
Fish	LC50	Fathead minnow (Pimephales promelas)	> 18 mg/l, 96 Hours
Other	EC50	Sewage microorganisms	> 1000 mg/kg, 3 Hours
Chronic			
Crustacea	LOEC	Daphnia magna	4.2 mg/l, 21 days
	NOEC	Daphnia magna	2.1 mg/l, 21 days
Fish	LOEC	Fathead minnow (Pimephales promelas)	1.3 mg/l, 32 days
	NOEC	Fathead minnow (Pimephales promelas)	0.6 mg/l, 32 days
Terrestrial			
Chronic			
Sediment	LOEC	Midge (Chironomus riparius)	> 706 mg/kg, 28 days
	NOEC	Midge (Chironomus riparius)	706 mg/kg, 28 days

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) 1.42, @ pH 7, 25C (shake-flask) 1.5, @ pH 9, 25C (shake-flask)

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

Baricitinib	2.71 - 3.02, 2 sludges 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 Not available.

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)

Classified hazard categories 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

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 05-23-2018

Revision date 12-19-2018

Version # 05

List of abbreviations LEG: Lilly Exposure Guideline.
TWA: Time Weighted Average

Disclaimer

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