



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	Jaypirca™
<b>Other means of identification</b>	
<b>Item Code</b>	TA7026, TA6902, ZD6902, 703313, 703312, ZD7026, 703043, 703021, 702558, 702559, 702681, 702710, 702712, 702713
<b>Synonyms</b>	Loxo-305 Tablets * LY3527727 Tablets * 3527727 Tablets
<b>LY Number</b>	LY3527727
<b>Recommended use</b>	Pharmaceutical
<b>Recommended restrictions</b>	None known.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

<b>Company name</b>	Eli Lilly and Company	
<b>Address</b>	Lilly Corporate Center Indianapolis, IN 46285 United States	
<b>Telephone</b>	Phone:	+1-317-276-2000
<b>E-mail</b>	lilly_sds@lilly.com	
<b>Emergency phone number</b>	CHEMTREC:	+1-800-424-9300

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Reproductive toxicity	Category 1B
	Specific target organ toxicity, repeated exposure	Category 2
<b>OSHA defined hazards</b>	Not classified.	

#### Label elements



**Signal word** Danger

#### Hazard statement

H360	May damage the unborn child.
H373	May cause damage to organs (blood, eyes) 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.
P260	Do not breathe dust.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

##### Response

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

P405	Store locked up.
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##### Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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**Hazard(s) not otherwise classified (HNOC)** None known.

## 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Pirtobrutinib	H-PYRAZOLE-4-CARBOXAMIDE, 5-AMINO-3-[4-[[[5-FLUORO-2-METHOXY BENZOYL)AMINO]METHYL]PHENYL]-1- (1S)-2,2,2-TRIFLUORO-1-METHYLETHY L]- Loxo-305	2101700-15-4	22

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

#### 4. First-aid measures

<b>Inhalation</b>	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
<b>Skin contact</b>	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.
<b>Eye contact</b>	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.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	May cause harm to the unborn child. Prolonged or repeated exposure may cause: Blood effects. Eye effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	See Section 8 of the SDS for Personal Protective Equipment. Wear suitable protective clothing, gloves and eye/face protection.
<b>Methods and materials for containment and cleaning up</b>	Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

<b>Precautions for safe handling</b>	Minimize dust generation and accumulation. See Section 8 of the SDS for Personal Protective Equipment.
<b>Conditions for safe storage, including any incompatibilities</b>	Keep container tightly closed in a dry and well-ventilated place.

#### 8. Exposure controls/personal protection

##### Occupational exposure limits

###### Lilly (LEG)

###### Components

Pirtobrutinib (CAS  
2101700-15-4)

###### Type

TWA (12hrs)

TWA (8hrs)

###### Value

3 µg/m3

4 µg/m3

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

<b>Exposure guidelines</b>	Health Based Excursion Limit: Maintain Full Shift TWA
<b>Appropriate engineering controls</b>	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).
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemical resistant gloves.
<b>Other</b>	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
<b>Respiratory protection</b>	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.
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Blue
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not applicable.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	No test data available.

### Upper/lower flammability or explosive limits

<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.

<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.

<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.

<b>Partition coefficient (n-octanol/water)</b>	Not available.
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<b>Auto-ignition temperature</b>	Not available.
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<b>Decomposition temperature</b>	Not available.
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<b>Viscosity</b>	Not available.
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### Other information

<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
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<b>Chemical stability</b>	Material is stable under normal conditions.
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<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
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<b>Conditions to avoid</b>	Contact with incompatible materials.
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<b>Incompatible materials</b>	Strong oxidizing agents.
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<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.
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## 11. Toxicological information

### Information on toxicological effects

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

Components	Species	Test Results
Pirtobrutinib (CAS 2101700-15-4)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rat	> 2000 mg/kg (no mortality)
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg (no mortality)
<b>Skin corrosion/irritation</b>	Rat: Slight irritation. (Pirtobrutinib) Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Bovine Corneal Opacity and Permeability assay: No eye irritation. (Pirtobrutinib) Based on available data, the classification criteria are not met.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.	
<b>Skin sensitization</b>	Due to lack of data the classification is not possible.	
<b>Germ cell mutagenicity</b>	In vivo micronucleus test: Negative. Mixed results in in vitro genetic toxicity assays. (Pirtobrutinib) Based on available data, the classification criteria are not met.	
<b>Carcinogenicity</b>	Not listed by IARC, NTP, ACGIH or OSHA. Due to lack of data the classification is not possible.	

#### 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** Embryo-lethality and fetal malformations reported in animal studies. (Pirtobrutinib)

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

**Specific target organ toxicity - repeated exposure** Animal studies have reported the following effects: Blood effects. Eye effects. Lymphoid organ effects. Mortality. (Pirtobrutinib)

**Aspiration hazard** Not applicable.

## 12. Ecological information

**Ecotoxicity** Harmful to aquatic life with long lasting effects.

Components	Species	Test Results	
Pirtobrutinib (CAS 2101700-15-4)			
<b>Aquatic</b>			
Algae	EC50	Algae	14.2 mg/l, 72 h (growth rate) (OECD 201)
			5.23 mg/l, 72 h (yield) (OECD 201)
	NOEC	Algae	0.5 mg/l, 72 h (yield and growth rate) (OECD 201)
Crustacea	EC50	Daphnia magna	11.16 mg/l, 48 h (OECD 202)
	NOEC	Daphnia magna	1.76 mg/l, 21 d (OECD 211)
Fish	LC50	Fathead minnow (Pimephales promelas)	> 15.7 mg/l, 96 h (OECD 203)
	NOEC	Fathead minnow (Pimephales promelas)	9.95 mg/l, 28 d (OECD 210)
Other	EC50	Sewage Microorganisms	> 1000 mg/l, 3 h (OECD 209)
	NOEC	Sewage Microorganisms	1000 mg/l, 3 h (OECD 209)

**Persistence and degradability** (Pirtobrutinib) Biodegradation: 11.8% in 28 days. (sewage sludge) (OECD 314B)  
DT50: 286 Days

(Pirtobrutinib) Degradation in aquatic sediment:  
DT50: 10.8 to 22 Days (water layer) (OECD 308)  
DT50: 18.7 to 185 Days (total system) (OECD 308)

#### Hydrolysis

##### Half-life (Hydrolysis)

Pirtobrutinib > 1 yr, (pH 4, 7, 9) (stable) (OECD 111) Estimated

**Bioaccumulative potential** See below.

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

Pirtobrutinib 2.757, (pH 9) (20°C)  
2.85, (pH 7)  
2.965, (pH 5)

**Mobility in soil** (Pirtobrutinib)  
Adsorption (Sludge) Koc: 114 to 234 L/kg (OECD 106)  
Adsorption (Soil) Koc: 414 to 768 L/kg (OECD 106)

**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 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.

#### 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)

##### 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 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](http://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** 01-30-2023

**Version #** 01

**List of abbreviations** ACGIH: American Conference of Governmental Industrial Hygienists.  
DOT: Department of Transportation (49 CFR 172.101)  
HEPA: High Efficiency Particulate Air.  
IARC: International Agency for Research on Cancer.  
IATA: International Air Transport Association.  
IMDG: International Maritime Dangerous Goods.  
LD50: Lethal Dose 50%.  
LEG: Lilly Exposure Guideline.  
NTP: National Toxicology Program.  
OSHA: Occupational Safety & Health Administration.  
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:  
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**Revision information** Product and Company Identification: Alternate Trade Names  
Exposure controls/personal protection: Respiratory protection  
Toxicological information: Mutagenicity