



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Retevmo™</b>
<b>Other means of identification</b>	
<b>Item Code</b>	703452, 703453, PU3977, PU2980, 702598, 702597, 702411, 702410
<b>Synonyms</b>	Loxo-292 Capsules
<b>LY Number</b>	LY3527723
<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>	Germ cell mutagenicity	Category 2
	Reproductive toxicity	Category 1B
	Specific target organ toxicity, single exposure	Category 2
	Specific target organ toxicity, repeated exposure	Category 2
<b>OSHA defined hazards</b>	Not classified.	

#### Label elements



<b>Signal word</b>	Danger
<b>Hazard statement</b>	
H341	Suspected of causing genetic defects.
H360	May damage fertility or the unborn child.
H371	May cause damage to organs (bone marrow).
H373	May cause damage to organs (gastrointestinal tract) through prolonged or repeated exposure.
<b>Precautionary statement</b>	
<b>Prevention</b>	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P281	Use personal protective equipment as required.
<b>Response</b>	
P308 + P313	IF exposed or concerned: Get medical advice/attention.
<b>Storage</b>	
P405	Store locked up.

## Disposal

P501

Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)**

None known.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Selpercatinib	6-(2-HYDROXY-2-METHYLPROPOXY)-4-(6-{6-[(6-METHOXYPYRIDIN-3-YL)METHYL]-3,6-DIAZABICYCLO[3.1.1]HEPTAN-3-YL}PYRIDIN-3-YL)PYRAZOLO[1,5-A]PYRIDINE-3-CARBONITRILE Loxo-292	2152628-33-4	30

### 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 heritable damage. Prolonged or repeated exposure may cause: Gastrointestinal effects.

### Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

### General information

The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

## 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

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. 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	Type	Value
Selpercatinib (CAS 2152628-33-4)	TWA (12hrs)	3 ug/m3
	TWA (8hrs)	5 ug/m3

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	Health Based Excursion Limit: Maintain Full Shift TWA (Selpercatinib)
<b>Appropriate engineering controls</b>	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).  The following are recommended for manufacturing or other situations where exposure to contents may occur.

### Individual protection measures, such as personal protective equipment

<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.  In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.
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## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Coarse Powder.
<b>Color</b>	White.

<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.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	Not water reactive.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing substances.
<b>Hazardous decomposition products</b>	Fire or excessive heat may produce hazardous decomposition products.

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
Selpercatinib (CAS 2152628-33-4)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rat	> 2000 mg/kg (no mortality)
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg (no mortality)

**Skin corrosion/irritation** Minimal to mild irritation with prolonged exposure. (Selpercatinib)  
Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Bovine Corneal Opacity and Permeability assay: No irritation (Selpercatinib)  
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** Local Lymph Node Assay (LLNA): Not a skin sensitizer. (Selpercatinib)  
Based on available data, the classification criteria are not met.

**Germ cell mutagenicity** Negative in in vitro genetic toxicity assays.  
In vivo micronucleus test: Positive. (Selpercatinib)

**Carcinogenicity** 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** Experiments in pregnant laboratory animals have demonstrated embryo lethality and fetal malformations. These effects indicate a potential for harm to the unborn child.  
Experiments in sexually mature laboratory animals have demonstrated testicular degeneration and abnormal sperm in males, and ovarian atrophy and fewer estrous cycles in females. These effects indicate a potential to impair fertility in males and females. (Selpercatinib)

**Specific target organ toxicity - single exposure** Animal studies have reported the following effects: Bone marrow changes. (Selpercatinib)

**Specific target organ toxicity - repeated exposure** Animal studies have reported the following effects: Bone marrow changes. Gastrointestinal effects. Changes in male reproductive organs. Changes in female reproductive organs. (Selpercatinib)

<b>Aspiration hazard</b>	Not applicable.
<b>Further information</b>	The most common effects reported with therapeutic administration were dry mouth, diarrhea, fatigue, constipation, headache, and hypertension.

## 12. Ecological information

**Ecotoxicity** Very toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Selpercatinib (CAS 2152628-33-4)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Algae	> 1.7 mg/l, 72 h (OECD 201) (yield and growth rate)
	NOEC	Algae	1.7 mg/l, 72 h (OECD 201) (yield and growth rate)
Crustacea	EC50	Daphnia magna	1.3 mg/l, 48 h (OECD 202)
Fish	LC50	Fathead minnow	> 1.9 mg/l, 96 h (OECD 203)
Other	EC50	Sewage Microorganisms	> 1000 mg/l, 3 h (OECD 209)
	NOEC	Sewage Microorganisms	1000 mg/l, 3 h (OECD 209)
<i>Chronic</i>			
Crustacea	NOEC	Daphnia magna	0.097 mg/l, 21 d (OECD 211)
Fish	NOEC	Fathead minnow	0.16 mg/l, 28 d (OECD 210)

**Persistence and degradability** Biodegradation: 70% in 28 days. (OECD 314B) (Selpercatinib)  
DT50: 3.46 Days (OECD 314B) (Selpercatinib)

Degradation in aquatic sediment:  
DT50: 0.39 to 0.75 Days (water layer) (OECD 308) (Selpercatinib)  
DT50: 159 to 121 Days (total system) (OECD 308) (Selpercatinib)

### Hydrolysis

#### Half-life (Hydrolysis)

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

**Bioaccumulative potential** See below.

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

Selpercatinib 1.3, (pH 5)  
3.08, (pH 7)  
3.45, (pH 9)

**Mobility in soil** Adsorption (Sludge) Koc: 683 to 1180 L/kg (OECD 106) (Selpercatinib)  
Adsorption (Soil) Koc: 116050 to 582830 L/kg (OECD 106) (Selpercatinib)

**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

**UN number** UN3077  
**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Selpercatinib)  
**Transport hazard class(es)**  
**Class** 9  
**Subsidiary risk** -  
**Packing group** III  
**Environmental hazards** Yes  
**ERG Code** 9L  
**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

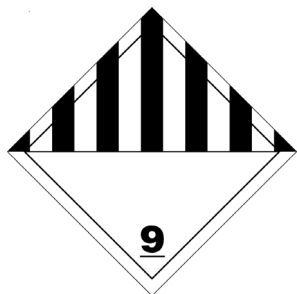
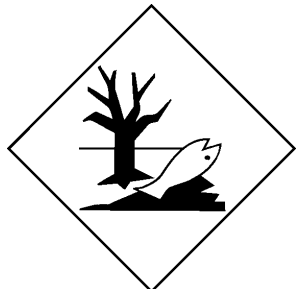
**Other information**

**Passenger and cargo aircraft** Allowed with restrictions.  
**Cargo aircraft only** Allowed with restrictions.

**IMDG**

**UN number** UN3077  
**UN proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Selpercatinib)  
**Transport hazard class(es)**  
**Class** 9  
**Subsidiary risk** -  
**Packing group** III  
**Environmental hazards**  
**Marine pollutant** Yes  
**EmS** F-A, S-F  
**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

**IATA; IMDG****Marine pollutant****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** Germ cell mutagenicity  
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.

**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** 05-27-2020**Revision date** 01-04-2022**Version #** 06**List of abbreviations**

ACGIH: American Conference of Governmental Industrial Hygienists.  
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.  
 DOT: Department of Transportation (49 CFR 172.101).  
 EC50: Effective Concentration 50%.  
 ECHA: European Chemical Agency.  
 GHS: Globally Harmonized System of Classification and Labeling of Chemicals.  
 HEPA: High Efficiency Particulate Air.  
 IARC: International Agency for Research on Cancer.  
 IATA: International Air Transport Association.  
 IMDG Code: International Maritime Dangerous Goods Code.  
 LD: Lethal Dose.  
 LD50: Lethal Dose 50%.  
 LEG: Lilly Exposure Guideline.  
 NIOSH: National Institute for Occupational Safety & Health.  
 NTP: National Toxicology Program.  
 OSHA: Occupational Safety & Health Administration.  
 RID: Regulations concerning the international carriage of dangerous goods by rail (Règlement International concernant le transport de marchandises dangereuses par chemin de fer).  
 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.

For additional information contact:

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**Revision information**

Hazard(s) identification: Hazard statement  
 GHS: Classification