



SAFETY DATA SHEET

1. Identification

Product identifier	Retevmo™
Other means of identification	
Item Code	PU3977, PU2980, 702598, 702597, 702411, 702410
Synonyms	Loxo 292 Capsules
LY Number	LY3527723
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	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
OSHA defined hazards	Not classified.	

Label elements



Signal word Danger

Hazard statement

H341	May form combustible dust concentrations in air.
H360	Suspected of causing genetic defects.
H371	May damage fertility or the unborn child.
H373	May cause damage to organs (bone marrow).
	May cause damage to organs (gastrointestinal tract) through prolonged or repeated exposure.

Precautionary statement

Prevention

P260	Do not breathe dust.
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 + P311	IF exposed or concerned: Call a POISON CENTER/doctor.
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Storage

Not available.

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.

Supplemental information None.

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 None known.

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

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Health Based Excursion Limit: Maintain Full Shift TWA (Selpercatinib)
Appropriate engineering controls	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

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	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.
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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.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Capsule
Color	Grey and Light blue.

Odor Not available.

Odor threshold Not available.

pH Not available.

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 test data available.

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)	Not available.
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	Not oxidizing.

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	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)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg (no mortality)
Oral		
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)
Aspiration hazard	Not applicable.
Further information	The most common effects reported with therapeutic administration were dry mouth, diarrhea, fatigue, constipation, headache, and hypertension.

12. Ecological information

Ecotoxicity	This material has not been tested for environmental effects.
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)

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

Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international regulations.
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14. Transport information

DOT	Not regulated as dangerous goods.
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IATA	Not regulated as dangerous goods.
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IMDG	Not regulated as dangerous goods.
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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
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15. Regulatory information

US federal regulations	This product is 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)

Classified hazard categories	Germ cell mutagenicity Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
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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.

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

Version # 01

List of abbreviations DOT: Department of Transportation (49 CFR 172.101).
IATA: International Air Transport Association.
IMDG Code: International Maritime Dangerous Goods Code.
LEG: Lilly Exposure Guideline.
LD: Lethal Dose.
LD50: Lethal Dose 50%.
TWA: Time Weighted Average Value.

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For additional information contact:
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Revision information Product and Company Identification: Product and Company Identification
Hazard(s) identification: Prevention
First-aid measures: General information
Exposure controls/personal protection: Exposure guidelines
Physical and chemical properties: Color
Toxicological information: Reproductivity
Other information, including date of preparation or last revision: Disclaimer