

1. Identification

Product identifier	Retevmo Tablets	
Other means of identification		
SDS number	7561	
Item Code	TA5562, TA6120, TA6082, TA5340, 703224, 703223, 703222, 703221, 703083, 703082, 703081, 703080	
Synonyms	Loxo-292 Tablets	
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	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.	
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.	
P270	Do not eat, drink or smoke when using this product.	
P264	Wash thoroughly after handling.	
P281	Use personal protective equipment as required.	
Response		
P308 + P311	IF exposed or concerned: Call a POISON CENTER/doctor.	
Storage		
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.
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	40

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 liquid to an unconscious person. 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	See Section 8 of the SDS for Personal Protective Equipment. Wear suitable protective clothing, gloves and eye/face protection.
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.

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 Tablet.
Color Blue, Grey, Purple or Pink

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

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

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 Results in genetic toxicity assays (in vitro): Negative
In vivo micronucleus test: Positive. (Selpercatinib)

Carcinogenicity In a 2-year carcinogenicity study, no carcinogenic effects observed in male rats. Low incidence of vaginal tumors reported in female rats at the high dose. The relevance of these rodent tumors to humans is not known. (Selpercatinib)
Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

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 Very toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Selpercatinib (CAS 2152628-33-4)			
Aquatic			
<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 hazard -
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)

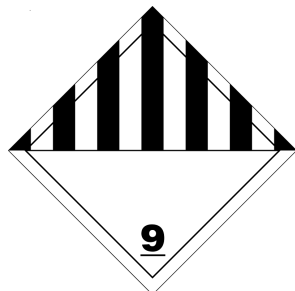
Class 9
Subsidiary hazard -
Packing group III
Environmental hazards
Marine pollutant Yes

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.

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.

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 07-30-2024

Version # 01

List of abbreviations

CEN: European Committee for Standardization.
DOT: Department of Transportation.
DT50 (Sediment): Time to disappearance of 50% of parent.
DT50 (Sludge): Time to degradation of 50% of parent.
EC50: Effective Concentration 50%.
HEPA: High Efficiency Particulate Air.
IARC: International Agency for Research on Cancer.
IATA: International Air Transport Association.
IMDG: International Maritime Dangerous Goods.
LC50: Lethal Concentration 50%.
LD50: Lethal Dose 50%.
LEG: Lilly Exposure Guideline.
LLNA: Local Lymph Node Assay.
MARPOL: International Convention for the Prevention of Pollution from Ships.
NIOSH: National Institute for Occupational Safety & Health.
NOEC: No observed effect concentration.
NTP: National Toxicology Program.
OECD: Organization for Economic Cooperation and Development.
OSHA: Occupational Safety & Health Administration.
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.
TWA: Time Weighted Average.
vPvB: Very persistent and very bioaccumulative.

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
First-aid measures: Ingestion
Exposure controls/personal protection: Respiratory protection
Toxicological information: Carcinogenicity