



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Verzenio®</b>	
<b>Other means of identification</b>		
<b>Item Code</b>	702081, 702080, TA6216, TA5337, TA4815, TA4483, 703137, 703138, 703139, 703140, ZD0165, ZD0166, ZD0167, ZD0169	
<b>LY Number</b>	LY2835219	
<b>Recommended use</b>	Pharmaceutical	
<b>Recommended restrictions</b>	None known.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<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>	Acute toxicity, oral	Category 4
	Reproductive toxicity	Category 1B
	Specific target organ toxicity, repeated exposure	Category 2
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>		
H302	Harmful if swallowed.	
H360	May damage fertility or the unborn child.	
H373	May cause damage to organs 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.	
P280	Wear protective gloves/protective clothing/eye protection/face protection.	
<b>Response</b>		
P308 + P311	IF exposed or concerned: Call a POISON CENTER/doctor.	
<b>Storage</b>	Not available.	
<b>Disposal</b>	Not available.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.	
<b>Supplemental information</b>	None.	

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Abemaciclib	IUPAC Name: N-{{5-[(4-ETHYLPIPERAZIN-1-YL)METHYL]PYRIDIN-2-YL}-5-FLUORO-4-[4-FLUORO-2-METHYL-1-(1-METHYLETHYL)-1H-BENZIMIDAZOL-6-YL]PYRIMIDIN-2-AMINE	1231929-97-7	35.71

**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>	Harmful if swallowed. May cause reproductive effects. Prolonged exposure may cause chronic effects.
<b>Indication of immediate medical attention and special treatment needed</b>	None known
<b>General information</b>	The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Carbon dioxide, dry chemical or water.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Hazardous decomposition products formed under fire conditions.
<b>Special protective equipment and precautions for firefighters</b>	Wear self-contained breathing apparatus and protective clothing.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.
<b>Methods and materials for containment and cleaning up</b>	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. 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>	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. 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

	Type	Value
Abemaciclib (CAS 1231929-97-7)	TWA (12hrs)	1.4 ug/m3
	TWA (8hrs)	2 ug/m3

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Exposure guidelines

Health Based Excursion Limit: Maintain Full Shift TWA (Abemaciclib)

### 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).

### 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.

## 9. Physical and chemical properties

### Appearance

#### Physical state

Solid.

#### Form

Tablet.

#### Color

Pale Yellow to White.

#### Odor

Not available.

#### Odor threshold

Not available.

#### pH

Neutral

#### 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.

<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>	The substance or mixture is not classified as 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>	None known.
<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** Harmful if swallowed. (Abemaciclib)

Components	Species	Test Results
Abemaciclib (CAS 1231929-97-7)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rat	> 2000 mg/kg
<b>Oral</b>		
LD50	Mouse	> 150 mg/kg (mortality, 4-day study)
	Rat	> 50 mg/kg (no mortality)

**Skin corrosion/irritation** No effects identified in animal studies. (Abemaciclib)  
Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Bovine Corneal Opacity and Permeability assay: No eye irritation. (Abemaciclib)  
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 (Abemaciclib)  
Based on available data, the classification criteria are not met.

**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** Animal studies have reported the following effects: Decreased fetal weight. Increased fetal malformations. (Abemaciclib)

**Specific target organ toxicity - single exposure** No significant adverse effects reported. (Abemaciclib)  
Due to inconclusive data the classification criteria are not met.

**Specific target organ toxicity - repeated exposure** Animal studies have reported the following effects: Changes in male reproductive organs. Bone marrow changes. Blood effects (decreased red blood cell, white blood cell, and platelet counts). Kidney effects. Lymphoid tissue effects. Gastrointestinal effects. Lung effects. Eye effects. (Abemaciclib)

**Aspiration hazard** Not applicable.

## 12. Ecological information

### Ecotoxicity

Very toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Abemaciclib (CAS 1231929-97-7)			
<b>Aquatic</b>			
Algae	EC50	Green Algae ( <i>Pseudokirchneriella subcapitata</i> )	19 µg/l, 72 h (yield and growth rate)
	LOEC	Green Algae ( <i>Pseudokirchneriella subcapitata</i> )	14 µg/l, 72 h (yield and growth rate)
	NOEC	Green Algae ( <i>Pseudokirchneriella subcapitata</i> )	5.9 µg/l, 72 h (yield and growth rate)
Crustacea	EC50	<i>Daphnia magna</i>	> 43000 µg/l, 48 h (acute immobilization) 130 µg/l, 21 d (chronic growth, reproduction and survival)
	LOEC	<i>Daphnia magna</i>	50 µg/l, 21 d (chronic growth, reproduction and survival)
	NOEC	<i>Daphnia magna</i>	5600 µg/l, 48 h (acute immobilization) 20 µg/l, 21 d (chronic growth, reproduction and survival)
Fish	LC50	Fathead minnow ( <i>Pimephales promelas</i> )	6200 µg/l, 96 h (acute mortality)
	LOEC	Fathead minnow ( <i>Pimephales promelas</i> )	170 µg/l, 4 d + 28 day post-hatch (chronic growth and survival)
	NOEC	Fathead minnow ( <i>Pimephales promelas</i> )	1200 µg/l, 96 h (acute mortality) 75 µg/l, 4 d + 28 day post-hatch (chronic growth and survival)
Other	EC50	Sewage Microorganisms	> 1000000 µg/l, 3 h (respiration inhibition)
	NOEC	Sewage Microorganisms	1000000 µg/l, 3 h (respiration inhibition)
<b>Terrestrial</b>			
Sediment	EC50	Midge ( <i>Chironomus riparius</i> )	350000 ug/kg, 28 d (chronic emergence and development rate)
	LOEC	Midge ( <i>Chironomus riparius</i> )	410000 ug/kg, 28 d (chronic emergence and development rate)
	NOEC	Midge ( <i>Chironomus riparius</i> )	140000 ug/kg, 28 d (chronic emergence and development rate)
Soil	EC50	Soil Microorganisms	> 970 mg/kg, 28 d (carbon and nitrogen transformation)
	LC50	Collembola ( <i>Folsomia candida</i> )	> 970 mg/kg (chronic mortality and reproduction)
		Earthworm ( <i>Eisenia foetida</i> )	> 970 mg/kg, 14 d (acute mortality and weight change)
	LOEC	Collembola ( <i>Folsomia candida</i> )	> 970 mg/kg (chronic mortality and reproduction)
		Earthworm ( <i>Eisenia foetida</i> )	970 mg/kg, 14 d (acute mortality and weight change)
	NOEC	Collembola ( <i>Folsomia candida</i> )	970 mg/kg (chronic mortality and reproduction)
	Earthworm ( <i>Eisenia foetida</i> )	485 mg/kg, 14 d (acute mortality and weight change)	
	Soil Microorganisms	970 mg/kg, 28 d (carbon and nitrogen transformation)	

### LILLY AQUATIC EXPOSURE GUIDELINES:

#### Abemaciclib

Acute LAEG (at the edge of the acute mixing zone):

19 µg/l

**Abemaciclib**

Chronic LAEG (at the edge of the chronic mixing zone):

0.5 µg/l

Drinking water LAEG (at the point where surface water is taken for drinking water):

0.34 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)**

Abemaciclib

3.61, pH 7 at 25°C

4.22, pH 9 at 25°C

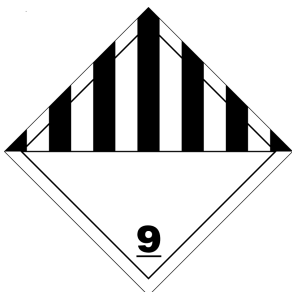
**Bioconcentration factor (BCF)**

Abemaciclib

181 - 240 L/KG

**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.**14. Transport information****DOT**

Not regulated as dangerous goods.

**IATA****UN number** UN3077**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Abemaciclib)**Transport hazard class(es)****Class** 9**Subsidiary risk** -**Packing group** III**Environmental hazards** Yes**ERG Code** 9L**Special precautions for user** Not available.**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. (Abemaciclib)**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** Not available.**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not available.**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

Acute toxicity (any route of exposure)  
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.

### 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** 05-20-2020

**Revision date** 07-08-2020

**Version #** 02

**List of abbreviations**  
EC50: Effective Concentration 50%.  
LC50: Lethal Concentration 50%.  
LD50: Lethal Dose 50%.  
LEG: Lilly Exposure Guideline.  
LOEC: Lowest observable effect concentration.  
NOEC: No observed effect concentration.  
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.

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**Revision information**

Toxicological information: Specific target organ toxicity - repeated exposure