SAFETY DATA SHEET

1. Identification

Product identifier: Verzenio®

Other means of identification:

- Item Code: 702081, 702080, TA6216, TA5337, TA4815, TA4483, 703137, 703138, 703139, 703140, ZD0165, ZD0166, ZD0167, ZD0169
- LY Number: LY2835219

Recommended use: Pharmaceutical

Recommended restrictions: None known.

Manufacturer/Importer/Supplier/Distributor information

- Manufacturer: 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:

- Acute toxicity, oral: Category 4
- Reproductive toxicity: Category 1B
- Specific target organ toxicity, repeated exposure: Category 2

OSHA defined hazards: Not classified.

Label elements

- Signal word: Danger
- Hazard statement:
  - H302: Harmful if swallowed.
  - H360: May damage fertility or the unborn child.
  - H373: May cause damage to organs 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 + P311: IF exposed or concerned: Call a POISON CENTER/doctor.
  - Storage: Not available.
  - Disposal: Not available.

Hazard(s) not otherwise classified (HNOC): None known.

Supplemental information: None.
3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abemaciclib</td>
<td>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</td>
<td>1231929-97-7</td>
<td>35.71</td>
</tr>
</tbody>
</table>

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
Harmful if swallowed. May cause reproductive effects. Prolonged exposure may cause chronic 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
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.

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. Wash hands thoroughly after handling. 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

<table>
<thead>
<tr>
<th>Lilly (LEG) Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abemaciclib (CAS 1231929-97-7)</td>
<td>TWA (12hrs)</td>
<td>1.4 ug/m3</td>
</tr>
<tr>
<td></td>
<td>TWA (8hrs)</td>
<td>2 ug/m3</td>
</tr>
</tbody>
</table>

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.
Decomposition temperature: Not available.
Viscosity: Not available.
Other information:
Explosive properties: Not explosive.
Oxidizing properties: The substance or mixture is not classified as 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: Harmful if swallowed. (Abemaciclib)

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abemaciclib (CAS 1231929-97-7)</td>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>&gt; 150 mg/kg (mortality, 4-day study)</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 50 mg/kg (no mortality)</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aquatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>EC50 Abemaciclib (CAS 1231929-97-7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Green Algae (Pseudokirchneriella subcapitata)</td>
<td>19 µg/l, 72 h (yield and growth rate)</td>
</tr>
<tr>
<td></td>
<td>LOEC Abemaciclib (CAS 1231929-97-7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Green Algae (Pseudokirchneriella subcapitata)</td>
<td>14 µg/l, 72 h (yield and growth rate)</td>
</tr>
<tr>
<td></td>
<td>NOEC Abemaciclib (CAS 1231929-97-7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Green Algae (Pseudokirchneriella subcapitata)</td>
<td>5.9 µg/l, 72 h (yield and growth rate)</td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50 Daphnia magna</td>
<td>&gt; 43000 µg/l, 48 h (acute immobilization)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>130 µg/l, 21 d (chronic growth, reproduction and survival)</td>
</tr>
<tr>
<td></td>
<td>LOEC Daphnia magna</td>
<td>50 µg/l, 21 d (chronic growth, reproduction and survival)</td>
</tr>
<tr>
<td></td>
<td>NOEC Daphnia magna</td>
<td>5600 µg/l, 48 h (acute immobilization)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20 µg/l, 21 d (chronic growth, reproduction and survival)</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50 Fathead minnow (Pimephales promelas)</td>
<td>6200 µg/l, 96 h (acute mortality)</td>
</tr>
<tr>
<td></td>
<td>LOEC Fathead minnow (Pimephales promelas)</td>
<td>170 µg/l, 4 d + 28 day post-hatch (chronic growth and survival)</td>
</tr>
<tr>
<td></td>
<td>NOEC Fathead minnow (Pimephales promelas)</td>
<td>1200 µg/l, 96 h (acute mortality)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>75 µg/l, 4 d + 28 day post-hatch (chronic growth and survival)</td>
</tr>
<tr>
<td>Other</td>
<td>EC50 Sewage Microorganisms</td>
<td>&gt; 1000000 µg/l, 3 h (respiration inhibition)</td>
</tr>
<tr>
<td></td>
<td>NOEC Sewage Microorganisms</td>
<td>1000000 µg/l, 3 h (respiration inhibition)</td>
</tr>
<tr>
<td><strong>Terrestrial</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sediment</td>
<td>EC50 Midge (Chironomus riparius)</td>
<td>3500000 ug/kg, 28 d (chronic emergence and development rate)</td>
</tr>
<tr>
<td></td>
<td>LOEC Midge (Chironomus riparius)</td>
<td>4100000 ug/kg, 28 d (chronic emergence and development rate)</td>
</tr>
<tr>
<td></td>
<td>NOEC Midge (Chironomus riparius)</td>
<td>14000000 ug/kg, 28 d (chronic emergence and development rate)</td>
</tr>
<tr>
<td>Soil</td>
<td>EC50 Soil Microorganisms</td>
<td>&gt; 970 mg/kg, 28 d (carbon and nitrogen transformation)</td>
</tr>
<tr>
<td></td>
<td>LC50 Collembola (Folsomia candida)</td>
<td>&gt; 970 mg/kg (chronic mortality and reproduction)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Earthworm (Eisenia foetida)</td>
</tr>
<tr>
<td></td>
<td>LOEC Collembola (Folsomia candida)</td>
<td>&gt; 970 mg/kg (chronic mortality and reproduction)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Earthworm (Eisenia foetida)</td>
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<tr>
<td></td>
<td>NOEC Collembola (Folsomia candida)</td>
<td>&gt; 970 mg/kg (chronic mortality and reproduction)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Earthworm (Eisenia foetida)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>485 mg/kg, 14 d (acute mortality and weight change)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Soil Microorganisms</td>
</tr>
</tbody>
</table>

**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) 9
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) 9
Class 9
Subsidiary risk -
Packing group III
Environmental hazards Yes
Marine pollutant
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
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.

- Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

<table>
<thead>
<tr>
<th>Classified hazard categories</th>
<th>Hazard categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (any route of exposure)</td>
<td>Reproductive toxicity</td>
</tr>
<tr>
<td>Specific target organ toxicity (single or repeated exposure)</td>
<td></td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>05-20-2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>07-08-2020</td>
</tr>
<tr>
<td>Version #</td>
<td>02</td>
</tr>
</tbody>
</table>

**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.

For additional information contact:
Eli Lilly and Company
Hazard Communication
+1-317-651-9533

Revision information

Toxicological information: Specific target organ toxicity - repeated exposure