1. Identification

Product identifier: Effient®

Other means of identification:
- Item Code: ZD4760, ZD5123, TA5121, CT4760, CT4759, CT5121, CT5122, CT5123, CT4761, TA4761, TA4759, TA4760
- Synonyms: Prasugrel Hydrochloride Tablets * LY640315 Hydrochloride Tablets

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_msds@lilly.com
- Emergency phone number: CHEMTREC: +1-800-424-9300

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Specific target organ toxicity, repeated exposure Category 1 (Blood)

OSHA defined hazards: Not classified.

Label elements

Signal word: Danger

Hazard statement:
- H372: Causes damage to organs (blood) through prolonged or repeated exposure.

Precautionary statement

Prevention:
- P260: Do not breathe dust.

Response:
- P314: Get medical advice/attention if you feel unwell.

Storage: Not available.

Disposal: Not available.

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

Supplemental information: None.

3. Composition/information on ingredients

Mixtures

Material name: Effient®

Version #: 03
Revision date: 09-23-2015
Issue date: 11-18-2014
### 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 delayed clotting of blood.

**Indication of immediate medical attention and special treatment needed**
Hypersensitivity including angioedema has been reported in patients receiving prasugrel including in patients with a history of hypersensitivity reaction to other thienopyridines.

**PRE-EXISTING MEDICAL CONDITIONS WHICH MAY BE AGGRAVATED BY EXPOSURE:**
Individuals on anticoagulant therapy.

### 5. Fire-fighting measures

**Suitable extinguishing media**
Carbon dioxide, dry chemical or water.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
Fire or excessive heat may produce hazardous decomposition products. If small particles are generated during further processing, handling, or by other means, may form combustible dust concentrations in air.

**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 following are recommended 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**
Minimize dust generation and accumulation. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.

**Conditions for safe storage, including any incompatibilities**
Store at 20 to 25 °C (68 to 77 °F). Excursions permitted from 15 to 30 °C (59 to 86 °F).

### 8. Exposure controls/personal protection

**Occupational exposure limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prasugrel hydrochloride (CAS 389574-19-0)</td>
<td>Excursion Limit</td>
<td>200 ug/m3</td>
<td>30 minutes</td>
</tr>
<tr>
<td></td>
<td>TWA (12hrs)</td>
<td>17 ug/m3</td>
<td></td>
</tr>
</tbody>
</table>
Lilly (LEG)
Components

<table>
<thead>
<tr>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA (8hrs)</td>
<td>25 ug/m³</td>
<td></td>
</tr>
</tbody>
</table>

### Biological limit values
No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls
Intact capsules or tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to contents may occur.

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/face shield.

#### 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.

#### Thermal hazards
Not available.

### 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**
  White to off-white.

- **Odor**
  Odorless

- **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)**
  Not 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.
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. (Active ingredient)

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prasugrel hydrochloride (CAS 389574-19-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal LD</td>
<td>Rabbit</td>
<td>&gt; 1000 mg/kg</td>
</tr>
<tr>
<td>Oral LD50</td>
<td>Rat</td>
<td>1000 - 2000 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Rabbit: No irritation (Active ingredient)
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation
Rabbit: Mild eye irritation. (Active ingredient)
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
Did not cause sensitization on laboratory animals. (Active ingredient)
Based on available data, the classification criteria are not met.

Germ cell mutagenicity
Result in genetic toxicity assays (in vitro and in vivo): Negative (Active ingredient)
Based on available data, the classification criteria are not met.

Carcinogenicity
Not listed by IARC, NTP, ACGIH or OSHA. Prasugrel was not carcinogenic in a 2-year rat carcinogenicity study. In a 2-year mouse carcinogenicity study, an increase in hepatocellular adenomas was observed in female mice in the 100- and 300-mg/kg groups and in male mice in the 300-mg/kg group. This effect is considered secondary to enzyme induction in these mice and not relevant to human safety. (Active ingredient)
Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity
Not available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens
Not available.

Reproductive toxicity
No significant effects on fertility, early embryonic development, embryo-fetal development, or pre-/postnatal development were observed in the rat or rabbit. At 300 mg/kg/day, a dose that caused decreased maternal body weight gain, a slight decrease in offspring body weight (relative to controls) was observed. (Active ingredient)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure
No effects identified in animal studies. (Active ingredient)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure
Repeat-dose testing in the rat, dog, and mouse demonstrated altered blood coagulation parameters and liver effects considered secondary to enzyme induction. (Active ingredient)

Aspiration hazard
Not applicable.
Chronic effects
Repeat-dose testing in the rat, dog, and mouse demonstrated altered blood coagulation parameters and liver effects considered secondary to enzyme induction. (Active ingredient)

12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prasugrel hydrochloride (CAS 389574-19-0)</td>
<td>Activated sludge of a predominantly domestic sewage</td>
<td>&gt; 10 mg/l, 3 hours (respiration inhibition)</td>
</tr>
<tr>
<td>Other</td>
<td>EC50</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Activated sludge of a predominantly domestic sewage</td>
</tr>
</tbody>
</table>

Acute

<table>
<thead>
<tr>
<th>Other</th>
<th>EC50</th>
<th>Pseudokirchnerella subcapitata</th>
<th>&gt; 1.2 mg/l, 72 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC</td>
<td>Pseudokirchnerella subcapitata</td>
<td>&gt;= 1.2 mg/l, 72 hours (average specific growth rate)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Activated sludge of a predominantly domestic sewage</td>
<td>0.25 mg/l, 72 hours (biomass)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NOEC</td>
<td>&gt;= 1.2 mg/l, 72 hours (biomass)</td>
</tr>
</tbody>
</table>

Aquatic

Acute

<table>
<thead>
<tr>
<th>Crustacea</th>
<th>EC50</th>
<th>Daphnia magna</th>
<th>&gt; 2 mg/l, 48 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC</td>
<td>Daphnia magna</td>
<td>&gt;= 2 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>Rainbow Trout</td>
<td>2.1 mg/l, 96 hours</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Rainbow Trout</td>
<td>1.4 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

Chronic

<table>
<thead>
<tr>
<th>Crustacea</th>
<th>EC50</th>
<th>Daphnia magna</th>
<th>1.2 mg/l, 21 days (reproduction)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LOEC</td>
<td>Daphnia magna</td>
<td>0.57 mg/l, 21 days</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Daphnia magna</td>
<td>0.28 mg/l, 21 days</td>
</tr>
<tr>
<td>Fish</td>
<td>LOEC</td>
<td>Fathead minnow (Pimephales promelas)</td>
<td>0.35 mg/l embryo + 28 days post hatch</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Fathead minnow (Pimephales promelas)</td>
<td>0.19 mg/l embryo + 28 days post hatch</td>
</tr>
</tbody>
</table>

Persistence and degradability

| Ready hydrolysis half-life @ 20C: | 2.29 (days), 0.83 (days), 0.85 (hours)(pH4, pH7, pH9) |
| Ready hydrolysis half-life @ 10C: | (Days): 4.59 (pH4) |
| (Hours): 51.3, 2.53 (pH7, pH9) | Biodegradation in sludge (65 days 14C-prasugrel): 100% disappearance within 15 minutes, 10% conversion to 14C-CO2 over 28 days |
| Degradation in aquatic sediment (100 days under aerobic conditions 14C-prasugrel): DT50: 0.54 to 0.63 days; 27.9 to 30.8% converted to 14C-CO2 over 100 days |

Bioaccumulative potential

Not available.

Partition coefficient n-octanol / water (log Kow)

| Prasugrel hydrochloride | 2.27, (Log POW @ pH 4) |
|                        | 3.8, (Log POW @ pH 7) |
|                        | 5.66, (Log POW @ pH 9) |

Mobility in soil

Not available.

Other adverse effects

Not available.

Ecotoxicological Properties

Drinking Water

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prasugrel hydrochloride</td>
<td>2.5 µg/l, (Lilly aquatic exposure guideline)</td>
</tr>
</tbody>
</table>
Chronic Exposure of Aquatic Organisms
Components                      Test Results
Prasugrel hydrochloride          3 µg/l, (Lilly aquatic exposure guideline)

Acute Exposure of Aquatic Organisms
Components                      Test Results
Prasugrel hydrochloride          81 µg/l, (Lilly aquatic exposure guideline)

13. Disposal considerations
Disposal instructions Dispose in accordance with all applicable regulations.

14. Transport information
DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

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

15. Regulatory information
US federal regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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 1910.1001-1050)
Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

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
US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)
Not listed.

US. Massachusetts RTK - Substance List
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law
Not listed.
US. Rhode Island RTK
Not regulated.

US. California Proposition 65
Not Listed.

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

Issue date: 11-18-2014
Revision date: 09-23-2015
Version #: 03

Lilly Lab Code
Health: 1
Fire: 1
Reactivity: 0

List of abbreviations
LAEG: Lilly Aquatic Exposure Guideline
LEG: Lilly Exposure Guideline
TWA: Time Weighted Average

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 MATERIAL 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
Product and Company Identification: Product Codes
GHS: Qualifiers