



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Effient®</b>
<b>Other means of identification</b>	
<b>Item Code</b>	ZD4760, ZD5123, TA5123, TA5121, CT4760, CT4759, CT5121, CT5122, CT5123, CT4761, TA4761, TA4759, TA4760
<b>Synonyms</b>	Prasugrel Hydrochloride Tablets * LY640315 Hydrochloride Tablets
<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_msds@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>	Specific target organ toxicity, repeated exposure	Category 1 (Blood)
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	
H372	Causes damage to organs (blood) through prolonged or repeated exposure.
<b>Precautionary statement</b>	
<b>Prevention</b>	
P260	Do not breathe dust.
<b>Response</b>	
P314	Get medical advice/attention if you feel unwell.
<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	%
Prasugrel hydrochloride	Ethanone, 2-[2-(acetyloxy)-6,7-dihydrothieno [3,2-c]pyridin-5(4H)-yl]-1-cyclopropyl-2-(2-fluorophenyl)-, hydrochloride 5-[(1R)-2-cyclopropyl-1-(2-fluorophenyl)-2-oxoethyl]-4,5,6,7-tetrahydrothieno[3,2-c]pyridin-2-yl acetate hydrochloride	389574-19-0	4 - 7

#### 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>	May cause delayed clotting of blood.
<b>Indication of immediate medical attention and special treatment needed</b>	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

<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>	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.
<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 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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

<b>Precautions for safe handling</b>	Minimize dust generation and accumulation. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.
<b>Conditions for safe storage, including any incompatibilities</b>	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

##### Lilly (LEG)

##### Components

Components	Type	Value	Form
Prasugrel hydrochloride (CAS 389574-19-0)	Excursion Limit	200 ug/m3	30 minutes
	TWA (12hrs)	17 ug/m3	

Lilly (LEG) Components	Type	Value	Form
	TWA (8hrs)	25 ug/m3	
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).		
<b>Appropriate engineering controls</b>	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).		
<b>Individual protection measures, such as personal protective equipment</b>			
<b>Eye/face protection</b>	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.		
<b>Skin protection</b>			
<b>Hand protection</b>	Chemical resistant gloves.		
<b>Other</b>	Chemical-resistant gloves and impermeable body covering to minimize skin contact.		
<b>Respiratory protection</b>	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.		
<b>Thermal hazards</b>	Not available.		
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	White to off-white.

<b>Odor</b>	Odorless
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.

<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.

<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 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** Based on available data, the classification criteria are not met. (Active ingredient)

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
Prasugrel hydrochloride (CAS 389574-19-0)		
<b>Acute</b>		
<b>Dermal</b>		
LD	Rabbit	> 1000 mg/kg
<b>Oral</b>		
LD50	Rat	1000 - 2000 mg/kg
<b>Skin corrosion/irritation</b>	Rabbit: No irritation (Active ingredient) Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Rabbit: Mild eye irritation. (Active ingredient) Based on available data, the classification criteria are not met.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.	
<b>Skin sensitization</b>	Did not cause sensitization on laboratory animals. (Active ingredient) Based on available data, the classification criteria are not met.	
<b>Germ cell mutagenicity</b>	Result in genetic toxicity assays (in vitro and in vivo): Negative (Active ingredient) Based on available data, the classification criteria are not met.	
<b>Carcinogenicity</b>	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.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Not available.		
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Not listed.		
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Not available.		
<b>Reproductive toxicity</b>	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.	
<b>Specific target organ toxicity - single exposure</b>	No effects identified in animal studies. (Active ingredient) Based on available data, the classification criteria are not met.	
<b>Specific target organ toxicity - repeated exposure</b>	Repeat-dose testing in the rat, dog, and mouse demonstrated altered blood coagulation parameters and liver effects considered secondary to enzyme induction. (Active ingredient)	
<b>Aspiration hazard</b>	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**

Components		Species	Test Results
Prasugrel hydrochloride (CAS 389574-19-0)			
Other	EC50	Activated sludge of a predominantly domestic sewage	> 10 mg/l, 3 hours (respiration inhibition)
	NOEC	Activated sludge of a predominantly domestic sewage	>= 10 mg/l, 3 hours (respiration inhibition)
<i>Acute</i>			
Other	EbC50	Pseudokirchnerella subcapitata	> 1.2 mg/l, 72 hours
	ErC50	Pseudokirchnerella subcapitata	> 1.2 mg/l, 72 hours
	LOEC	Pseudokirchnerella subcapitata	1.2 mg/l, 72 hours (biomass)
	NOEC	Pseudokirchnerella subcapitata	>= 1.2 mg/l, 72 hours (average specific growth rate) 0.25 mg/l, 72 hours (biomass)
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Daphnia magna	> 2 mg/l, 48 hours
	NOEC	Daphnia magna	>= 2 mg/l, 48 hours
Fish	LC50	Rainbow Trout	2.1 mg/l, 96 hours
	NOEC	Rainbow Trout	1.4 mg/l, 96 hours
<i>Chronic</i>			
Crustacea	EC50	Daphnia magna	1.2 mg/l, 21 days (reproduction) > 1.2 mg/l, 21 days (survival)
	LOEC	Daphnia magna	0.57 mg/l, 21 days
	NOEC	Daphnia magna	0.28 mg/l, 21 days
	Fish	LOEC	Fathead minnow (Pimephales promelas)
NOEC		Fathead minnow (Pimephales promelas)	0.19 mg/l embryo + 28 days post hatch

**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  
(Active ingredient)

**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****Components****Test Results**

Prasugrel hydrochloride

2.5 µg/l, (Lilly aquatic exposure guideline)

## Chronic Exposure of Aquatic Organisms

### Components

Prasugrel hydrochloride

### Test Results

3 µg/l, (Lilly aquatic exposure guideline)

## Acute Exposure of Aquatic Organisms

### Components

Prasugrel hydrochloride

### Test Results

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**

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** 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:

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+1-317-651-9533**Revision Information**Product and Company Identification: Product Codes  
GHS: Qualifiers