SAFETY DATA SHEET

1. Identification

Product identifier **Effient®**

Other means of identification

Item Code ZD4760, ZD5123, TA5123, TA5121, CT4760, CT4759, CT5121, CT5122, CT5123, CT4761, TA4761, TA4759, TA4760

Synonyms Prasugrel Hydrochloride Tablets * LY640315 Hydrochloride Tablets

LY Number LY640315

Recommended use Pharmaceutical

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Eli Lilly and Company

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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

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

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 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

Lilly (LEG)

Components	Type	Value	Form
Prasugrel hydrochloride (CAS 389574-19-0)	Excursion Limit	200 ug/m3	30 minutes
	TWA (12hrs)	17 ug/m3	
	TWA (8hrs)	25 ug/m3	

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

Appropriate engineering controls 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/faceshield.

Skin protection

Hand protection Chemical resistant gloves.

Other Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. 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.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	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)

Components	Species	Test Results
Prasugrel hydrochloride (CAS 389574-19-0)		
Acute		
Dermal		
LD	Rabbit	> 1000 mg/kg
Oral		
LD50	Rat	1000 - 2000 mg/kg

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 listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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

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)
Acute			
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)
Aquatic			
Acute			
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
Chronic			
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)	0.35 mg/l embryo + 28 days post hatch
	NOEC	Fathead minnow (Pimephales promelas)	0.19 mg/l embryo + 28 days post hatch

LILLY AQUATIC EXPOSURE GUIDELINES:

Prasugrel hydrochloride

Acute LAEG (at the edge of the acute mixing zone):	81 µg/l
Chronic LAEG (at the edge of the chronic mixing zone):	3 µg/l
Drinking water LAEG (at the point where surface water is taken for drinking water):	2.5 µg/l

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)

Partition coefficient n-octanol / water (log Kow)

Prasugrel hydrochloride	5.66, (Log POW @ pH 9)

Mobility in soil Not available.

Other adverse effects Not available.

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.

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 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Classified hazard categories 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 11-18-2014

Revision date 02-26-2019

Version # 04

List of abbreviations

LAEG: Lilly Aquatic Exposure Guideline.
LEG: Lilly Exposure Guideline.
TWA: Time Weighted Average

Disclaimer

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