

EFFIENT TABLETS

Version 1.6

Revision Date 06/08/2010

Print Date 06/28/2010

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : EFFIENT TABLETS
Substance Number : 000004280239
Common Name : Prasugrel Hydrochloride Tablets

Chemical Name : Ethanone, 2-[2-(acetyloxy)-6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl]-1-cyclopropyl-2-(2-fluorophenyl)-, hydrochloride
LY Number : LY640315 hydrochloride tablets

Company : Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Telephone : 317-276-2000
Emergency telephone : CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

Item Code : TA4760, TA4759, TA4761, CT4761, CT5123, CT5122, CT5121, CT4759, CT4760, TA5121

SECTION 2. HAZARDS IDENTIFICATION**Emergency Overview****Lilly Lab Labeling Code****Health:** 1**Fire:** 1**Reactivity:** 0**Primary Hazards:** Not hazardous if intact, Blood**Hazard Summary (Caution):** Not hazardous if intact. May cause delayed clotting of blood.**Emergency Overview**

Form : tablet
Colour : White to off-white
Odour : odourless

Potential Health Effects

Aggravated Medical Condition : Individuals on anticoagulant therapy.

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Primary Routes of Entry : Inhalation Skin contact

Additional Information : Intact capsules or tablets are not considered hazardous under normal handling procedures. May cause delayed clotting of blood. May cause headache and dizziness. Animal studies have reported the following effects: Liver effects.

Carcinogenicity

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Concentration [%]
Prasugrel Hydrochloride	389574-19-0	4 - 7
Excipients	NA	93 - 97

NA = Not applicable, Not assigned, or Not available.

SECTION 4. FIRST AID MEASURES

Inhalation : Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Call a physician immediately.

Skin contact : Wash off immediately with plenty of water for at least 15 minutes. Take off all contaminated clothing immediately. 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. Obtain medical attention.

Ingestion : If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a physician immediately.

SECTION 5. FIRE-FIGHTING MEASURES

Flash point : not applicable

Upper explosion limit : no data available

Lower explosion limit : no data available

Suitable extinguishing media : Water Carbon dioxide (CO2) Dry chemical

Unusual Fire and Explosion : Dust may form explosive mixture in air. Hazardous decomposition products formed

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Hazard. under fire conditions.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Methods for cleaning up : The following are recommended for manufacturing or other situations where exposure to contents may occur. Do not sweep. Preferred method for spill cleanup is by using a HEPA equipped vacuum. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear protective equipment to avoid exposure (see Section 8 for specific handling precautions).

SECTION 7. HANDLING AND STORAGE**Storage**

Requirements for storage areas and containers : Store at 20 to 25 C (68 to 77 F). Excursions permitted from 15 to 30 C (59 to 86 F).

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Exposure guidelines**

Components	Exposure Limit Values
Prasugrel Hydrochloride	LEG: 12 hour TWA 17 $\mu\text{g}/\text{m}^3$ (Prasugrel)
	LEG: 8 hour TWA 25 $\mu\text{g}/\text{m}^3$ (Prasugrel)
	LEG: 30 min Excursion Limit 200 $\mu\text{g}/\text{m}^3$ (Prasugrel)

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.

Engineering measures

Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, isolator (eg. glovebag, glovebox), or closed material transfer systems.

Personal protective equipment

Respiratory protection : Use an approved respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.

Eye protection : Goggles Face-shield

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Skin and body protection : Chemical-resistant gloves and impermeable body covering to minimize skin contact.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**Appearance**

Form	: tablet	Colour	: White to off-white
Physical state	: solid	Odour	: odourless

Safety data

Flash point	: not applicable	Upper explosion limit	: no data available
Lower explosion limit	: no data available	Water solubility	: no data available

SECTION 10. STABILITY AND REACTIVITY

Materials to avoid : Strong oxidizing agents

Hazardous decomposition products : Hazardous decomposition products formed under fire conditions.

Thermal decomposition : Stable under normal conditions.

Hazardous reactions : Hazardous polymerisation does not occur.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute oral toxicity**

• Prasugrel Hydrochloride: LD50 (rat) 1,000 - 2,000 mg/kg

Acute dermal toxicity

• Prasugrel Hydrochloride: LD50 (rabbit) > 1,000 mg/kg

Skin irritation

• Prasugrel Hydrochloride: rabbit, No irritation

Eye irritation

• Prasugrel Hydrochloride: rabbit, Mild eye irritation

Sensitisation

• Prasugrel Hydrochloride: Did not cause sensitization on laboratory animals. (Prasugrel)

Repeated dose toxicity

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- Prasugrel Hydrochloride:

Repeat-dose testing in the rat, dog, and mouse demonstrated altered blood coagulation parameters and liver effects considered secondary to enzyme induction.

Carcinogenicity

- Prasugrel Hydrochloride:

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.

Reproductive toxicity

- Prasugrel Hydrochloride:

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.

Mutagenicity

- Prasugrel Hydrochloride:

Result in genetic toxicity assays (in vitro and in vivo): Negative. (Prasugrel)

SECTION 12. ECOLOGICAL INFORMATION

Toxicity to fish

- Prasugrel Hydrochloride

LC50 / 96 h / *Oncorhynchus mykiss* (rainbow trout): 2.1 mg/l
 NOEC / 96 h / *Oncorhynchus mykiss* (rainbow trout): 1.4 mg/l
 LOEC (embryo + 28 days post hatch) / *Pimephales promelas* (fathead minnow): 0.35 mg/l
 NOEC (embryo + 28 days post hatch) / *Pimephales promelas* (fathead minnow): 0.19 mg/l

Toxicity to algae

- Prasugrel Hydrochloride

EC50 / 72 h / *Pseudokirchneriella subcapitata* (green algae): > 1.2 mg/l (biomass)
 EC50 / 72 h / *Pseudokirchneriella subcapitata* (green algae): > 1.2 mg/l (average specific growth rate)
 LOEC / 72 h / *Pseudokirchneriella subcapitata* (green algae): 1.2 mg/l (biomass)
 NOEC / 72 h / *Pseudokirchneriella subcapitata* (green algae): 0.25 mg/l (biomass)
 NOEC / 72 h / *Pseudokirchneriella subcapitata* (green algae): >= 1.2 mg/l (average specific growth rate)

Effects on micro-organisms

- Prasugrel Hydrochloride

EC50 / 3 h / Respiration inhibition of activated sludge: > 10 mg/l
 NOEC / 3 h / Respiration inhibition of activated sludge: >= 10 mg/l

Toxicity to daphnia

- Prasugrel Hydrochloride

EC50 / 48 h / *Daphnia magna* (Water flea) : > 2 mg/l

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NOEC / 48 h/ Daphnia magna (Water flea)
>= 2.0 mg/l

Chronic Toxicity to daphnia

- Prasugrel Hydrochloride

LOEC/ 21 d / Daphnia magna (Water flea) : 0.57 mg/l
NOEC/ 21 d / Daphnia magna (Water flea) : 0.28 mg/l
EC50/ 21 d / Daphnia magna (Water flea) : > 1.2 mg/l
(survival)
EC50/ 21 d / Daphnia magna (Water flea) : 1.2 mg/l
(reproduction)

Lilly Aquatic Exposure Guideline

- Prasugrel Hydrochloride

Additional Ecological Information**Prasugrel Hydrochloride****Environmental Fate:**

Ultraviolet-visible absorption spectra (% theoretical phototransformation in 1 month):
77, 96, 55 (pH4, pH7, pH9)

Dissociation constant (pKa): 5.21

Ready hydrolysis half-life @ 20C:

(Days): 2.29, 0.83, 0.85 (pH4, pH7, pH9)

Ready hydrolysis half-life @ 10C:

(Days): 4.59 (pH4)

(Hours): 51.3, 2.53 (pH7, pH9)

Adsorption to sewage sludge:

(Kd): 92 to 329

(Koc): 252 to 905

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 0.65 days; 27.8 to 30.8% converted to 14C-CO2 over 100 days

SECTION 13. DISPOSAL CONSIDERATIONS

Waste disposal methods : In accordance with local and national regulations.

SECTION 14. TRANSPORT INFORMATION

Other information : Not dangerous goods in the meaning of DOT, IMO/IMDG, ICAO/IATA

SECTION 15. REGULATORY INFORMATION

TSCA Status: Not On TSCA Inventory

389574-19-0

Prasugrel Hydrochloride

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DSL Status: This product contains the following components that are not on the Canadian DSL nor NDSL lists.
389574-19-0 Prasugrel Hydrochloride

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SECTION 16. OTHER INFORMATION

Further information

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 MERCHANT ABILITY 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
317-651-9533