



SAFETY DATA SHEET

1. Identification

Product identifier	Cymbalta (32%) Capsules	
Other means of identification		
Item Code	UC9671, PU3271, UC9670, PU3270	
Synonyms	2-Thiophenepropanamine, N-methyl-gamma-(1-naphthalenyloxy)-, hydrochloride (gammaS)-	
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	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 1
	Reproductive toxicity	Category 2
	Reproductive toxicity	Effects on or via lactation
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
	Specific target organ toxicity, repeated exposure	Category 2 (liver)
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger	
Hazard statement		
H302	Harmful if swallowed.	
H318	Causes serious eye damage.	
H336	May cause drowsiness or dizziness.	
H361	Suspected of damaging fertility or the unborn child.	
H362	May cause harm to breast-fed children.	
H373	May cause damage to organs (Liver) 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.	
P263	Avoid contact during pregnancy/while nursing.	
P280	Wear protective gloves/protective clothing/eye protection/face protection.	
Response		
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	

P308 + P313

IF exposed or concerned: Get medical advice/attention.

Storage

Not available.

Disposal

Not available.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Not applicable.

3. Composition/information on ingredients**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
Duloxetine Hydrochloride	LY248686 Hydrochloride (3S)-N-methyl-3-(naphthalen-1-yloxy)-3-thiophen-2-ylpropan-1-amine hydrochloride 2-Thiophenepropanamine, N-methyl-gamma-(1-naphthalenyloxy)-, hydrochloride, (gammaS)-	136434-34-9	32
Other components below reportable levels			68

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 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

Causes eye burns. May cause reproductive effects.

Indication of immediate medical attention and special treatment needed

No specific antidote is known. An airway should be established. Monitoring of cardiac and vital signs is recommended, along with appropriate symptomatic and supportive measures. Gastric lavage may be indicated if performed soon after ingestion or in symptomatic patients. Activated charcoal may be useful in limiting absorption. Duloxetine has a large volume of distribution and forced diuresis, hemoperfusion, and exchange perfusion are unlikely to be beneficial.

General information

Capsules and tablets are intended for human consumption under guidance of a physician. Capsules or tablets are not considered hazardous under normal handling procedures.

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

Lilly (LEG)

Components

	Type	Value
Duloxetine Hydrochloride (CAS 136434-34-9)	Excursion Limit	300 ug/m3
	TWA (12hrs)	25 ug/m3
	TWA (8hrs)	40 ug/m3

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 recommendations in this section are intended 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, local exhaust ventilation, or down-draft booth.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear goggles/face shield.

Skin protection

Hand protection

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

Other

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

Respiratory protection

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

Thermal hazards

Not available.

General hygiene considerations

In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

9. Physical and chemical properties

Appearance

Physical state

Solid.

Form

Capsules

Color

No data available.

Odor

Odorless

Odor threshold

No data available.

pH

No data available.

Melting point/freezing point

No data available.

Initial boiling point and boiling range

No data available.

Flash point

Not applicable.

Evaporation rate

Not available.

Flammability (solid, gas)

No test data available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

No data available.

Flammability limit - upper (%)

No data available.

Explosive limit - lower (%)

No data available.

Explosive limit - upper (%)

No data available.

Vapor pressure

Not available.

Vapor density	Not available.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	Not available.
Other information	
Density	No data available.
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	Stable at normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing substances.
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.

11. Toxicological information

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components	Species	Test Results
Duloxetine Hydrochloride (CAS 136434-34-9)		
Acute		
Dermal		
LD	Rabbit	> 1000 mg/kg
Oral		
LD50	Rat	491 mg/kg , (male) (Tremors. Convulsions) 279 mg/kg , (female) (Tremors. Convulsions)

Skin corrosion/irritation Rabbit: Slight irritation. (Duloxetine Hydrochloride)
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Rabbit: Corrosive. (Duloxetine Hydrochloride)

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Negative in active systemic anaphylaxis and passive cutaneous anaphylaxis tests. (Duloxetine Hydrochloride)
Based on available data, the classification criteria are not met.

Germ cell mutagenicity In vitro and in vivo tests did not show mutagenic effects. (Duloxetine)
Based on available data, the classification criteria are not met.

Carcinogenicity Not listed by IARC, NTP, ACGIH or OSHA.
Duloxetine was administered in the diet to rats and mice for 2 years. In rats, duloxetine did not increase the incidence of tumors. In female mice, there was an increased incidence of hepatocellular adenomas and carcinomas at the high dose only (144 mg/kg/day), but these were considered to be secondary to hepatic enzyme induction and not relevant to human risk.
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

Duloxetine administered to rats at doses up to 45 mg/kg/day did not affect male or female mating or fertility. There was no evidence of teratogenicity in animal studies. When duloxetine was administered orally to pregnant rats throughout gestation and lactation, decreases in maternal body weights and food consumption were observed, and the survival of pups to 1 day postpartum and pup body weights at birth and during the lactation period were decreased at a dose of 30 mg/kg/day; the no-effect dose was 10 mg/kg/day. Furthermore, behaviors consistent with increased reactivity, such as increased startle response to noise and decreased habituation of locomotor activity, were observed in pups following maternal exposure to 30 mg/kg/day. Post-weaning growth and reproductive performance of the progeny were not affected adversely by maternal duloxetine treatment. Duloxetine and/or its metabolites are excreted into the milk of lactating rats.

Specific target organ toxicity - single exposure

May cause drowsiness or dizziness. (Duloxetine Hydrochloride)

Specific target organ toxicity - repeated exposure

Dilation of the pupil and slow pupillary light response reported in dogs administered 3 mg/kg/day orally for 1 year. Liver effects (tissue changes, enzyme induction) was reported in rats administered up to 0.08% in diet (47 mg/kg/day) for 6 months and dogs dosed orally with 10 mg/kg/day or more for one year. (Duloxetine Hydrochloride)

Aspiration hazard

No aspiration toxicity classification

Further information

Capsules and tablets are intended for human consumption under guidance of a physician. Intact capsules or tablets are not considered hazardous under normal handling procedures. Adverse events commonly observed during therapeutic administration of Duloxetine include nausea, dry mouth, constipation, decreased appetite, fatigue, dizziness, drowsiness, headache, insomnia, and increased sweating. In animal studies, the major signs of overdose toxicity would be related to the central nervous (tremors, clonic convulsions, ataxia) and gastrointestinal (emesis, decreased appetite) systems.

12. Ecological information

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

Components	Species	Test Results
Duloxetine Hydrochloride (CAS 136434-34-9)		
<i>Acute</i>		
	EC50	> 1000000 ug/kg, 14 d , Eisenia fetida (earthworms) 36500 µg/l, 3 hr , Respiration inhibition of activated sludge (1.5 g solids/L)
Other	EC50	Pseudokirchnerella subcapitata 200 µg/l, 72 hr , (average specific growth rate) 64 µg/l, 72 hr , (biomass)
<i>Chronic</i>		
	NOEC	92000 ug/kg, 28 d , C. riparius (highest concentration tested) 2000 µg/l, 3 hr , Respiration inhibition of activated sludge
Other	NOEC	Pseudokirchnerella subcapitata 7 µg/l, 72 hr , (average specific growth rate) 4.3 µg/l, 72 hr , (biomass)
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Daphnia magna 2400 µg/l, 48 hr 280 µg/l, 21 d , (reproduction)
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss) 1300 µg/l, 96 hr
	NOEC	Fathead minnow (Pimephales promelas) 12 µg/l, 28 d , (embryo and 28 days post hatch)

Components	Species	Test Results
<i>Chronic</i> Crustacea	NOEC Daphnia magna	1100 µg/l, 48 hr 11 µg/l, 21 d
Persistence and degradability	Aerobic degradation in sewage sludge (8 days): not significant Aerobic degradation in aquatic sediment(100 days): 5-11% CO2 evolution DT50 from overlying water: 3 days Up to 45 degradation products observed DT50 from total water-sediment system: 78 and 241 days(2 different water systems evaluated) Photolysis: Theoretical loss of 100% over 1 month Hydrolysis half-life: 30 C: 42, 101, 72 days (pH 4, 7, 9) 40 C: 16, 32, 23 days (pH 4, 7, 9)	
Bioaccumulative potential	log Kow: < 4.	
Partition coefficient n-octanol / water (log Kow)		
Duloxetine Hydrochloride		0.781 (pH 4) 1.54 (pH 9) 3.35 (pH 7)
Bioconcentration factor (BCF)		
Duloxetine Hydrochloride		324
Mobility in soil	Not available.	
Other adverse effects	Not available.	

Ecotoxicological Properties

Drinking Water

Components

Duloxetine Hydrochloride

Test Results

20 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms

Components

Duloxetine Hydrochloride

Test Results

1.7 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components

Duloxetine Hydrochloride

Test Results

15 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

UN number

UN3077

UN proper shipping name

Environmentally hazardous substance, solid, n.o.s. (Duloxetine Hydrochloride)

Transport hazard class(es)

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.

Cargo aircraft only

Allowed.

IMDG

UN number

UN3077

UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Duloxetine Hydrochloride)

Transport hazard class(es)

Class 9

Subsidiary risk -

Packing group III

Environmental hazards

Marine pollutant Yes

EmS F-A, S-F

Special precautions for user Not available.

Transport in bulk according to Not available.

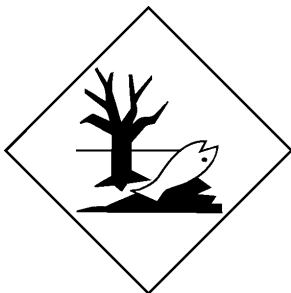
Annex II of MARPOL 73/78 and

the IBC Code

IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

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 - Yes

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 California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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 09-04-2014

Revision date 09-24-2015

Version # 04

Lilly Lab Code Health: 3
Fire: 1
Reactivity: 0

List of abbreviations

LEG: Lilly Exposure Guideline
NOEC: No Observed Effect Concentration
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.

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Revision Information GHS: Qualifiers