



SAFETY DATA SHEET

1. Identification

Product identifier	Strattera® Capsules
Other means of identification	
Item Code	ZD3227, ZD3239, ND1063, UC9547, ND1090, ND1101, ND1064, ND1103, PU3251, UC9550, UC9546, ND1104, ND1102, UC9548, ND1062, PU3226, UC9549, PU3250, PU3229, PU3239, PU3225, ND1061, PU3238, PU3227, B02453, B02455, B02457, B02459, B02490, TP5800, TP5801, TP5802
Synonyms	Benzenepropanamine, N-methyl-gamma-(2-methylphenoxy)-, hydrochloride, (gammaR)- * (-)-N-Methyl-3-phenyl-3-(ortho-tolyloxy)-propylamine hydrochloride
LY Number	LY404363
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
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
	Specific target organ toxicity, repeated exposure	Category 2
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.
H373	May cause damage to organs (Liver) through prolonged or repeated exposure.

Precautionary statement

Prevention

P264	Wash thoroughly after handling.
P260	Do not breathe dust.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Response

P330
P305 + P351 +
P338

Rinse mouth.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER/doctor.

P310

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	%
Atomoxetine Hydrochloride	LY404363 hydrochloride (3R)-N-methyl-3-(2-methylphenoxy)-3-ph enylpropan-1-amine hydrochloride Benzenepropanamine, N-methyl-gamma-(2-methylphenoxy)-, hydrochloride, (gammaR)-	82248-59-7	2 - 33

Composition comments

Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation

Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.

Skin contact

Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.

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. Call a physician or poison control center immediately.

Ingestion

Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.

Most important symptoms/effects, acute and delayed

Harmful if swallowed. Causes serious eye damage. May cause drowsiness or dizziness. May cause damage to organs (Liver) through prolonged or repeated exposure.

Indication of immediate medical attention and special treatment needed

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. Because atomoxetine is highly protein-bound, dialysis is not likely to be useful in the treatment of overdose.

General information

The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

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

Do not sweep. Vacuum material with appropriate dust collection filter in place. 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

Atomoxetine Hydrochloride
(CAS 82248-59-7)

TWA (12hrs)

25 ug/m3

TWA (8hrs)

38 ug/m3

Biological limit values

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

Appropriate engineering controls

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

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

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

Capsule

Color

White to off-white. (ingredients)
Blue (capsules)

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 applicable.

Evaporation rate

Not available.

Flammability (solid, gas)

No test data 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)

Soluble in water.

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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

11. Toxicological information

Information on toxicological effects

Acute toxicity Harmful if swallowed. The formulated material is not expected to pose an inhalation hazard.

Components	Species	Test Results
Atomoxetine Hydrochloride (CAS 82248-59-7)		
Acute		
Dermal		
LD	Rabbit	> 200 mg/kg
Inhalation		
LC50	Rat	330 mg/m3, 4 h racemic mixture
Oral		
LD	Dog	> 37.5 mg/kg Tremors. Myoclonic jerking. Dilated pupils.
LD50	Rat	> 300 mg/kg (fed) Mortality. Myoclonic jerking. 196 mg/kg fasted
Other		
LD50	Rat	25 mg/kg Intravenous

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

Serious eye damage/eye irritation Rabbit: Corrosive.
Immediate rinsing may prevent permanent damage. (Atomoxetine hydrochloride)

Respiratory or skin sensitization

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

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

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

Carcinogenicity No evidence of carcinogenicity reported in two-year studies at dietary concentrations up to 0.1% (rats) and 0.3% (mice). (Atomoxetine hydrochloride)
Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity	Slight fertility effects reported in a 1-generation fertility study in rats. However, fertility findings were not duplicated in a subsequent 2-generation study at equivalent doses and route of administration. Embryo-fetal developmental toxicity studies in rats and rabbits indicate that atomoxetine is not teratogenic or embryotoxic. Study results indicate that atomoxetine administered to young rats causes a slight delay in puberty and in epididymal sperm counts but that these effects have no impact on reproduction. (Atomoxetine hydrochloride) Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	May cause drowsiness or dizziness. Tremors. Elevated blood pressure. Increased heart rate. (Atomoxetine hydrochloride)
Specific target organ toxicity - repeated exposure	Hepatotoxicity (increased liver weight, hepatocellular vacuolation, increased serum ALT) was reported in male rats given dietary concentrations greater than or equal to 0.01% for 3 or 12 months and in mice given 0.4% in diet for 3 months. No hepatotoxicity was observed in dogs administered up to 16 mg/kg/day for 3 or 12 months. Clinical signs (pupillary light response, tremors, dilated pupils) were observed in dogs given less than 8 mg/kg/day for 1 year. Young rats administered up to 50 mg/kg/day from 10 days of age through adulthood matured physically and behaviorally with no major organ toxicity. (Atomoxetine hydrochloride)
Aspiration hazard	No aspiration toxicity classification (Atomoxetine hydrochloride)
Further information	The most commonly reported symptoms accompanying acute and chronic overdoses were gastrointestinal symptoms, somnolence, dizziness, tremor, and abnormal behavior. Hyperactivity and agitation have also been reported. Signs and symptoms consistent with mild to moderate sympathetic nervous system activation (e.g., tachycardia, blood pressure increased, mydriasis, dry mouth) were also observed. Most events were mild to moderate. (Atomoxetine hydrochloride)

12. Ecological information

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Components	Species	Test Results
Atomoxetine Hydrochloride (CAS 82248-59-7)		
<i>Acute</i>		
	EC50	73.1 mg/l, 3 h (Respiration inhibition of activated sludge) (Atomoxetine)
	NOEC	12.5 mg/l, 3 h (Respiration inhibition of activated sludge) (Atomoxetine)
Other	EC50	Pseudokirchnerella subcapitata 0.73 mg/l, 72 h (average specific growth rate) (Atomoxetine)
	NOEC	Pseudokirchnerella subcapitata 0.42 mg/l, 72 h (biomass) (Atomoxetine) 0.26 mg/l, 72 h (biomass) (Atomoxetine) 0.26 mg/l, 72 h (average specific growth rate) (Atomoxetine)
<i>Chronic</i>		
	LOEC	C. riparius > 77 mg/kg, 28 d (Full Life-Cycle Toxicity) (Atomoxetine)
	NOEC	C. riparius 77 mg/kg, 28 d (Full Life-Cycle Toxicity) (Atomoxetine)
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Daphnia magna 5.7 mg/l, 48 h (Atomoxetine)
	NOEC	Daphnia magna 0.49 mg/l, 48 h (Atomoxetine)
Fish	LC50	Rainbow Trout 8.8 mg/l, 96 h (Atomoxetine)
	NOEC	Rainbow Trout 3.6 mg/l, 96 h (Atomoxetine)
<i>Chronic</i>		
Crustacea	LOEC	Daphnia magna 0.95 mg/l, 21 d (Atomoxetine)
	NOEC	Daphnia magna 0.47 mg/l, 21 d (Atomoxetine)
Fish	LOEC	Fathead minnow (Pimephales promelas) 0.09 mg/l (embryo + 28 days post hatch) (Atomoxetine)

Components	Species	Test Results
NOEC	Fathead minnow (<i>Pimephales promelas</i>)	0.032 mg/l (embryo + 28 days post hatch) (Atomoxetine)

A LAEG is the maximum allowable concentration at the point of application that is expected to result in no appreciable risk to populations of aquatic and terrestrial organisms, or to human health. All data is for Atomoxetine.

LILLY AQUATIC EXPOSURE GUIDELINES:

Atomoxetine Hydrochloride

Drinking water LAEG (at the point where surface water is taken for drinking water):	4.8 µg/l
Chronic LAEG (at the edge of the chronic mixing zone):	3.2 µg/l
Acute LAEG (at the edge of the acute mixing zone):	219 µg/l

Persistence and degradability

Atomoxetine:
Sludge biodegradation (96-hour batch method, aerobic, 2.5 g/L activated sludge solids)

Half-life of atomoxetine: 136 hours

>1.92% CO₂ evolution
24.5% metabolite formation
Degradation in aquatic sediment (100 days, static, aerobic):
0.3% to 0.9% CO₂ evolution

Half-life from overlying water: < 3 days

Half-life from water/sediment system: 289 to 630 days

Hydrolysis: <10% over 5 days at 50C
Photolysis: not expected

Bioaccumulative potential

log Kow: < 4.

Partition coefficient n-octanol / water (log Kow)

Atomoxetine Hydrochloride	0.104, (pH 4) (as free base)
	0.676, (pH 7) (as free base)
	2.81, (pH 9) (as free base)

Mobility in soil

No data available.

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

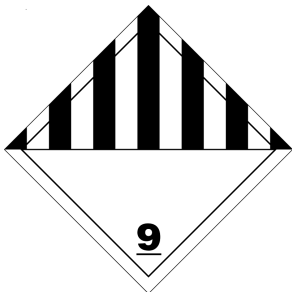
UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Atomoxetine Hydrochloride)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
ERG Code	9L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

IMDG

UN number	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Atomoxetine 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 Annex II of MARPOL 73/78 and the IBC Code Not applicable.

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.

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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Classified hazard categories

Acute toxicity (any route of exposure)
Serious eye damage or eye irritation
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.

US state regulations

California Proposition 65

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.

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 09-25-2015

Revision date 10-09-2019

Version # 11

List of abbreviations DOT: Department of Transportation (49 CFR 172.101).
EC50: Effective Concentration 50%.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IATA: International Air Transport Association.
IMDG Code: International Maritime Dangerous Goods Code.
LAEG: Lilly Aquatic Exposure Guideline.
LC50: Lethal Concentration 50%.
LD50: Lethal Dose 50%.
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 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:
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Revision information Physical and chemical properties: Form