SAFETY DATA SHEET

1. Identification

Product identifier **Strattera® Capsules**

Other means of identification

Item Code 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

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
Acute toxicity, inhalation	Category 3
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.
H331 Toxic if inhaled.
H336 May cause drowsiness or dizziness.
H373 May cause damage to organs (Liver) through prolonged or repeated exposure.

Precautionary statement

Prevention

P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P284 Wear respiratory protection.

Response

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
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	(3R)-N-methyl-3-(2-methylphenoxy)-3-phenylpropan-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. Call a physician or poison control center 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. Get medical attention 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 (Atomoxetine hydrochloride) Causes eye burns. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause drowsiness or dizziness. Elevated blood pressure. Increased heart rate.

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 Intact capsules or tablets are not considered hazardous under normal handling procedures. 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 Water. Carbon dioxide (CO2). Dry chemical.

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.

General fire hazards No unusual fire or explosion hazards noted.

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. 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 Prevent further leakage or spillage if safe to do so. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

7. Handling and storage

Precautions for safe handling Avoid contact with skin, eyes and clothing. Do not breathe dust. Wear personal protective equipment. 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 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, 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 Capsules

Color White to off-white. (ingredients)
Blue (Capsules)

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 No data available.

Evaporation rate No data 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	No data available.
Vapor density	No data 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	No data available.
Other information	
Density	No data available.
Explosive properties	Not explosive
Oxidizing properties	No oxidizing properties.
Potential for dust explosion	No data 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 agents.
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.

11. Toxicological information

Information on toxicological effects

Acute toxicity Harmful if swallowed. Toxic if inhaled.

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 available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

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 hepatoxicity 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)			
Acute			
	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)
			0.42 mg/l, 72 h (biomass) (Atomoxetine)
	NOEC	Pseudokirchnerella subcapitata	0.26 mg/l, 72 h (biomass) (Atomoxetine)
			0.26 mg/l, 72 h (average specific growth rate) (Atomoxetine)
Chronic			
	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			
Acute			
Crustacea	EC50	Daphnia magna	5.7 mg/l, 48 h (Atomoxetine)
	NOEC	Daphnia magna	0.49 mg/l, 48 h (Atomoxetine)

Components		Species	Test Results
Fish	LC50	Rainbow Trout	8.8 mg/l, 96 h (Atomoxetine)
	NOEC	Rainbow Trout	3.6 mg/l, 96 h (Atomoxetine)
Chronic			
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)
	NOEC	Fathead minnow (Pimephales promelas)	0.032 mg/l (embryo + 28 days post hatch) (Atomoxetine)

Persistence and degradability Atomoxetine:

Sludge biodegration (96-hour batch method, aerobic, 2.5 g/L activated sludge solids)
Half-life of atomoxetine: 136 hours
1.92% CO_2 evolution
24.5% metabolite formation
Degradation in aquatic sediment(100 days, static, aerobic)
0.3% to 0.9% CO_2 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. (Atomoxetine Hydrochloride)

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.

Ecotoxicological Properties

Drinking Water

Components	Test Results
Atomoxetine Hydrochloride	4.8 µg/l, (Atomoxetine)

Chronic Exposure of Aquatic Organisms

Components	Test Results
Atomoxetine Hydrochloride	3.2 µg/l, (Atomoxetine)

Acute Exposure of Aquatic Organisms

Components	Test Results
Atomoxetine Hydrochloride	219 µg/l, (Atomoxetine)

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 Read safety instructions, SDS and emergency procedures before handling.

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. (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	Read safety instructions, SDS and emergency procedures before handling.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not available.

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.
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

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 09-25-2015

Version # 01

Lilly Lab Code

Health: 3
Fire: 1
Reactivity: 0

List of abbreviations

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 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.

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Revision Information

Product and Company Identification: Alternate Trade Names
Hazard(s) identification: Response