



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. Immediately call a POISON CENTER or doctor/physician.
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	(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)		
<u>Acute</u>		
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 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)			
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)
<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)
	NOEC	Fathead minnow (Pimephales promelas)	0.032 mg/l (embryo + 28 days post hatch) (Atomoxetine)

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. (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

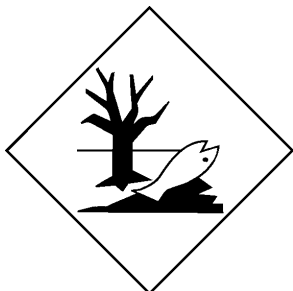
UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Atomoxetine Hydrochloride)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards Yes
ERG Code 9L
Special precautions for user Read safety instructions, SDS and emergency 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.

For additional information contact:
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Revision Information Product and Company Identification: Alternate Trade Names
Hazard(s) identification: Response