Answers That Matter.

STRATTERA CAPSULES

Version 1.5 | Revision Date 01/14/2010 | Print Date 06/28/2010

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	STRATTERA CAPSULES
Substance Number	:	000004274867
Common Name	:	Atomoxetine Hydrochloride Capsules
Chemical Name	:	Benzenepropanamine, N-methyl-gamma-(2-methylphenoxy)-, hydrochloride, (gammaR)-
Alternate Chemical Name	:	(-)-N-Methyl-3-phenyl-3-(ortho-tolyloxy)-propylamine hydrochloride
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	:	ND1063, UC9547, ND1090, ND1101, ND1064, ND1103, PU3251, UC9550, UC9546, ND1104, ND1102, UC9548, ND1062, PU3226, UC9549, PU3250, PU3229, PU3239, PU3225, ND1061, PU3238, PU3228, PU3227, B02453, B02455, B02457, B02459, B02490, TP5800, TP5801, TP5802

SECTION 2. HAZARDS IDENTIFICATION

Emergency Overview

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

Primary Hazards: Not hazardous if intact, Corrosive (eyes), Nervous System, Heart

Hazard Summary (Caution): Not hazardous if intact. Causes eye burns. May cause nervous system effects. May cause heart effects.

Emergency Overview

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

Potential Health Effects

Ingestion	:	Effects of exposure to contents: Harmful if swallowed.
Inhalation	:	Effects of exposure to contents: May be fatal if inhaled.
Aggravated Medical Condition	:	Individuals with cardiovascular disease, glaucoma, or on monoamine oxidase inhibitor (MAOI) therapy.
Primary Routes of Entry	:	Inhalation Skin contact
Additional Information	:	Effects of exposure to contents: Effects of exposure may include: Gastrointestinal effects. Tiredness. Dizziness. Elevated blood pressure. Increased heart rate. Animal studies have reported the following effects: Liver effects. Tremors.

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 [%]
Atomoxetine Hydrochloride	82248-59-7	2 - 33
Excipients	NA	71 - 98

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.

Notes to physician

Treatment	:	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.

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 Hazard. : Dust may form explosive mixture in air. Hazardous decomposition products formed 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/wet material and remove by mopping 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 : Keep container tightly closed in a dry and well-ventilated place.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure guidelines

Components	Exposure Limit Values
Atomoxetine Hydrochloride	**LEG:** 12 hour TWA 25 µg/m3 **LEG:** 8 hour TWA 38 µg/m3

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, local exhaust ventilation, or down-draft booth.

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

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

Safety data

Flash point	: not applicable	log Pow	: 0.104(pH 4)
Lower explosion limit	: no data available	log Pow	: 0.676(pH 7)
Upper explosion limit	: no data available	log Pow	: 2.81(pH 9)
Water solubility	: soluble		

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

- Atomoxetine Hydrochloride: LD50 (rat) 196 mg/kg

(fasted)
LD50 (rat) > 300 mg/kg
(fed)Mortality.Myoclonic jerking.
LD50 (dog) > 37.5 mg/kg
Tremors.Myoclonic jerking.Dilated pupils.

Acute inhalation toxicity

- Atomoxetine Hydrochloride: LC50 (rat) 330 mg/m3 (4 h)
(racemic mixture)

Acute dermal toxicity

- Atomoxetine Hydrochloride: LD50 (rabbit) > 200 mg/kg

Acute toxicity (other routes of administration)

- Atomoxetine Hydrochloride: Intravenous - LD50 (rat) 25 mg/kg

Skin irritation

- Atomoxetine Hydrochloride: rabbit, No irritation

Eye irritation

- Atomoxetine Hydrochloride: rabbit, Corrosive
(Injury was decreased if eyes were rinsed immediately after exposure.)

Repeated dose toxicity

- Atomoxetine Hydrochloride: 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.

Carcinogenicity

- Atomoxetine Hydrochloride: No evidence of carcinogenicity reported in two-year studies at dietary concentrations up to 0.1% (rats) and 0.3% (mice).

Reproductive toxicity

- Atomoxetine Hydrochloride: 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.

Mutagenicity

- Atomoxetine Hydrochloride: Result in genetic toxicity assays (in vitro and in vivo): Negative.

SECTION 12. ECOLOGICAL INFORMATION

Toxicity to fish

- Atomoxetine: LC50 / 96 h / Oncorhynchus mykiss (rainbow trout): 8.8 mg/l

Toxicity to algae

- Atomoxetine: EC50 / 72 h / Pseudokirchneriella subcapitata (green algae): 0.42 mg/l (biomass)
  EC50 / 72 h / Pseudokirchneriella subcapitata (green algae): 0.73 mg/l (average specific growth rate)
  NOEC / 72 h / Pseudokirchneriella subcapitata (green algae): 0.26 mg/l

Effects on micro-organisms

- Atomoxetine: EC50 / 3 h / Respiration inhibition of activated sludge: 73.1 mg/l (1.6 g solids/L)

Toxicity to daphnia

- Atomoxetine: EC50 / 48 h/ Daphnia magna (Water flea) : 5.7 mg/l

Chronic Toxicity to daphnia

- Atomoxetine: NOEC/ 21 d / Daphnia magna (Water flea) : 0.47 mg/l

Lilly Aquatic Exposure Guideline

- Atomoxetine: Drinking Water: 12.5 µg/l
  Chronic Exposure of Aquatic Organisms: 14 µg/l
  Acute Exposure of Aquatic Organisms: 120 µg/l

Additional ecological information

Atomoxetine
Fathead minnow early life stage toxicity test: no observable effect concentration: 32 microgram/L
C. riparius 28-day (sediment) chronic no observable effect concentration: >77 mg/kg
pKa: 9.23
Sludge adsorption (Koc, after 4 hours normalized to % organic carbon): 452 to 794
Sludge adsorption (Kd, after 4 hours): 211 to 370
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
23% transformation
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: 301 to 630 days
Hydrolysis: <10% over 5 days at 50C
Photolysis: not expected

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

IMDG

UN Number	:	3077
Description of the goods	:	Environmentally hazardous substance, solid, n.o.s. (atomoxetine hydrochloride)
Class	:	9
Packaging group	:	III
Labels	:	9
Marine pollutant	:	yes

Other information : Not dangerous goods in the meaning of DOT.

SECTION 15. REGULATORY INFORMATION

TSCA Status: Not On TSCA Inventory
82248-59-7 Atomoxetine Hydrochloride
Excipients

DSL Status: This product contains the following components that are not on the Canadian DSL nor NDSL lists.
82248-59-7 Atomoxetine Hydrochloride
Excipients

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.

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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