SAFETY DATA SHEETS

This SDS packet was issued with item:

078560219

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078560201 078560227 078560235 078568292

Reconcile Chewable Tablets

Version 1.8 | Revision Date 05/06/2011 | Print Date 09/18/2012

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Reconcile Chewable Tablets
Substance Number	:	000004273221
Common Name	:	Reconcile Chewable Tablets
Chemical Name	:	Benzenepropanamine, N-methyl-gamma-[4-(trifluoromethyl)phenoxy]-, hydrochloride
Use of the Substance/Mixture	:	Pharmaceutical

Company	:	Elanco Animal Health Division of Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285
Telephone	:	1-888-767-5023
Emergency telephone number	:	CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

Item Code	:	CA4203, CA4205, CA4207, CA4209

SECTION 2. HAZARDS IDENTIFICATION

Emergency Overview

Lilly Lab Labeling Code
Health: 2
Fire: 1
Reactivity: 0

Primary Hazards: Irritant (eyes, skin), Nervous System, Liver

Hazard Summary (Caution): Effects of exposure to contents: May cause eye and skin irritation. May cause nervous system effects. May cause liver effects.

Emergency Overview

Form	:	tablet
Colour	:	tan
Odour	:	Roast beef and liver

Potential Health Effects

Eyes	:	May cause eye irritation.

Skin	:	Contact dermatitis (rash) has been reported with occupational exposure to fluoxetine hydrochloride.
Ingestion	:	The most common adverse events reported with therapeutic administration include nausea, decreased appetite, anxiety, tremors, drowsiness, and sweating. The most common signs and symptoms associated with non-fatal overdosage were seizures, drowsiness, nausea, increased heart rate, and vomiting.
Aggravated Medical Condition	:	Acute overdose after sustained therapeutic exposure to fluoxetine hydrochloride has resulted in seizures. The potential for aggravation of a seizure disorder has not been ruled out.
Primary Routes of Entry	:	Inhalation Skin Absorption
Additional Information	:	This product is intended for animal consumption under guidance of a veterinarian.

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 [%]
Fluoxetine Hydrochloride	56296-78-7	4 - 5
Excipients	NA	95 - 96

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 : Cardiac and vital signs monitoring is recommended, along with general symptomatic and supportive measures. No specific antidote is known. Forced diuresis, dialysis, haemoperfusion, and exchange transfusion are unlikely to be of benefit. In limited human overdose experience, seizures have been reported. Appropriate seizure precautions are advised for any patient regularly taking fluoxetine who has been exposed to an acute overdose. Based on experience in animals, which may not be relevant to humans, fluoxetine-induced seizures that fail to remit spontaneously may respond to diazepam.

SECTION 5. FIRE-FIGHTING MEASURES

Flash point	: not applicable	Upper explosion limit	: no data available
Autoignition temperature	: no data available	Flammability (solid, gas)	: No test 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions : Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Environmental precautions : Try to prevent the material from entering drains or water courses. Refer to Sections 11 and 12 for health and environmental hazard information.

Methods for cleaning up : Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Clean up promptly by scoop or vacuum.

Additional advice : Refer to Sections 8, 11, 12 and 13 for more information.

SECTION 7. HANDLING AND STORAGE

Handling

Advice on safe handling : NOT FOR HUMAN USE! Keep out of the reach of children.

Storage

Requirements for storage areas and containers : Keep in a dry place. Keep container closed when not in use. Avoid moisture.

Storage temperature : 20 - 25 °C

Reconcile Chewable Tablets

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure guidelines

Components	Exposure Limit Values
Fluoxetine Hydrochloride	**LEG:** 12 hour TWA 30 µg/m3 **LEG:** 8 hour TWA 50 µg/m3

The following are recommended for manufacturing or other situations where exposure to contents may occur.

Engineering measures

Laboratory fume hood or local exhaust ventilation.

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	:	In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	: tablet	Colour	: tan
Physical state	: solid	Odour	: Roast beef and liver

Safety data

pH	: no data available	Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Melting point	: no data available	Lower explosion limit	: no data available
Boiling point	: no data available	Upper explosion limit	: no data available
Flash point	: not applicable	Vapour pressure	: no data available
Flammability (solid, gas)	: No test data available.	Specific Gravity	: no data available
		Water solubility	: soluble
Autoignition temperature	: no data available	Viscosity, dynamic	: no data available
		Relative vapour density	: no data available

Evaporation rate	: no data available	Odor Threshold	: no data available

SECTION 10. STABILITY AND REACTIVITY

Conditions to avoid	:	None known.
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
- Fluoxetine Hydrochloride: LD50 (rat) 451 mg/kg
  LD50 (mouse) 248 mg/kg
  LD50 (Monkey) > 50 mg/kg

Acute inhalation toxicity: Not relevant

Acute dermal toxicity
- Fluoxetine Hydrochloride: LD50 (rabbit) > 500 mg/kg

Skin irritation
- Fluoxetine Hydrochloride: rabbit, No skin irritation
  Skin irritation has been reported with occupational exposure.

Eye irritation
- Fluoxetine Hydrochloride: rabbit, Corrosive

Sensitisation
- Fluoxetine Hydrochloride: No test data available.

Repeated dose toxicity
- Fluoxetine Hydrochloride: Liver effects (reversible increases in serum enzymes, slight hepatic fat deposition, tissue changes).

Carcinogenicity
- Fluoxetine Hydrochloride: Did not show carcinogenic effects in animal experiments.

Reproductive toxicity

- Fluoxetine Hydrochloride: Two fertility studies conducted in adult rats indicated no adverse effects on fertility. In embryo-fetal development studies in rats and rabbits, there was no evidence of teratogenicity. However, in rat reproduction studies, an increase in stillborn pups, a decrease in pup weight, and an increase in pup deaths during the first 7 days postpartum occurred following maternal exposure to 7.5 mg/kg/day during gestation and lactation. There was no evidence of developmental neurotoxicity in the surviving offspring of rats. The no effect dose for rat pup mortality was 5 mg/kg/day.

  Data on a large number of exposed pregnancies in humans indicate no appearance of adverse effects on pregnancy or on the overall health of the fetus/newborn child. However, a few epidemiological studies have noted that some women treated with fluoxetine and other SSRIs late in the third trimester have had newborns with increased complications that could be consistent with drug discontinuation syndrome (e.g. transient jitteriness, difficulty feeding, tachypnea and irritability) and required prolonged hospitalizations.

Mutagenicity

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

Further information

- Fluoxetine Hydrochloride: In a juvenile toxicology study in rats, where the exposure period corresponds to human childhood and adolescence, administration of 30 mg/kg resulted in skeletal muscle necrosis. Other findings in rats included necrosis of the testis and immaturity and inactivity of the female reproductive tract. Following an approximate 11-week recovery period, sperm assessments indicated an approximately 30% decrease in sperm concentrations without affecting sperm morphology or motility. Microscopic evaluation indicated that testicular degeneration was irreversible. Delays in sexual maturation occurred with administration of 10 or 30 mg/kg. The significance of these findings in humans is unknown. Femur lengths at 30 mg/kg increased to a lesser extent compared with control rats.

SECTION 12. ECOLOGICAL INFORMATION

Toxicity to fish

- Fluoxetine Hydrochloride: LC50 / 96 h / Oncorhynchus mykiss (rainbow trout): 1.57 mg/l

Toxicity to algae

- Fluoxetine Hydrochloride: EC50 / Selenastrum capricornutum: 30.5 µg/l
  (average specific growth rate)
  NOEC / Selenastrum capricornutum: 1.2 µg/l

Effects on micro-organisms

- Fluoxetine Hydrochloride: IC50 / Fungus: 64 mg/l
  IC50 / mold: 64 mg/l
  IC50 / Bacteria (soil): 1,000 mg/l
  IC50 / Bacteria (n-fixing) (Azotobacter chroococcum): 64 mg/l
  IC50 / blue-green algae: 250 mg/l

Toxicity to daphnia

- Fluoxetine Hydrochloride — EC50 / 48 h/ Daphnia magna (Water flea) : 0.94 mg/l

Lilly Aquatic Exposure Guideline

- Fluoxetine Hydrochloride — Drinking Water: 11.2 µg/l
  Chronic Exposure of Aquatic Organisms: 1.2 µg/l
  Acute Exposure of Aquatic Organisms: 30.5 µg/l

Biodegradability

- Fluoxetine Hydrochloride

  Hydrolysis rate (1/day): 0,0, 0 (pH 5, 7, 9)
  Aerobic biodegradation half-life (days): not measurable

Bioaccumulation

- Fluoxetine Hydrochloride

  log Kow: < 4.

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

IATA	UN Number	:	3077
	Description of the goods	:	Environmentally hazardous substances, solid, n.o.s. (fluoxetine hydrochloride)
	Class	:	9
	Packaging group	:	III
	Labels	:	9
IMDG	UN Number	:	3077
	Description of the goods	:	Environmentally hazardous substances, solid, n.o.s. (fluoxetine 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
56296-78-7 Fluoxetine Hydrochloride

Reconcile Chewable Tablets

California Prop. 65
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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.
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