

SAFETY DATA SHEETS

This SDS packet was issued with item:

078933679

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

078933676 078933678 078933680 078941573 078941575 078941576 078941580 078945672



SAFETY DATA SHEET

Issue Date 20-Jul-2017

Revision Date 02-Nov-2017

Version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Reconcile (Fluoxetine Hydrochloride) Flavored Chewable Tablets

Other means of identification

Product Code PEG FP 10034057

Product Size 8 mg

ANADA Number 141-272

Recommended use of the chemical and restrictions on use

Recommended Use For the treatment of canine separation anxiety in conjunction with a behavior modification plan. This product is intended for animal consumption under guidance of a veterinarian.

Uses advised against No information available.

Details of the supplier of the safety data sheet

Supplier

Pegasus Laboratories, Inc.
8809 Ely Road
Pensacola, FL 32514

Manufacturer

Pegasus Laboratories, Inc.
8809 Ely Road
Pensacola, FL 32514

Company Name

Pegasus Laboratories, Inc.
8809 Ely Road
Pensacola, FL 32514

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin Corrosion/Irritation Category	Category 2
Serious eye damage/eye irritation	Category 2B
Specific target organ toxicity (single exposure)	Category 3

Label elements

Emergency Overview

Warning

Hazard statements

May cause eye irritation. May cause skin irritation. May cause respiratory irritation.



Appearance Round Tablet

Physical state Solid

Odor Roast Beef and Liver

Precautionary Statements - Prevention

- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood

- Use personal protective equipment as required
- Wash face, hands and any exposed skin thoroughly after handling
- Do not eat, drink or smoke when using this product
- Avoid breathing dust/fume/gas/mist/vapors/spray
- Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

- IF exposed or concerned: Get medical advice/attention
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- If eye irritation persists: Get medical advice/attention
- IF ON SKIN: Wash with plenty of soap and water
- Call a POISON CENTER or doctor/physician if you feel unwell
- Remove/Take off immediately all contaminated clothing
- Wash contaminated clothing before reuse
- IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- Call a POISON CENTER or doctor/physician if you feel unwell
- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
- Rinse mouth

Precautionary Statements - Storage

- Store locked up
- Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

- Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Per manufacturer guidance, this product is not considered hazardous when used as intended in its manufactured form. OSHA's Globally Harmonized System (GHS), which is based on overall hazard potential and is not risk-based, may assign classifications and hazards that could conflict with this statement. Do not use product in a manner inconsistent with product label/insert instructions.

Other Information

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS. Number	Weight %
Di-Tab (Dibasic Calcium Phosphate Dihydrate)	7789-77-7	20-50%
Sucrose	57-50-1	5-10%
Fluoxetin, HCl	5933-67-4	2-12%
Magnesium Stearate	557-04-0	0-2.5%

* The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES

First aid measures

General advice

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). If symptoms persist, call a physician.

Eye contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If symptoms persist, call a physician.

Skin Contact

Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. If symptoms persist, call a physician.

Inhalation

Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Move to

fresh air in case of accidental inhalation of vapors or decomposition products. If symptoms persist, call a physician.

Ingestion Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Call a physician immediately.

Self-protection of the first aider Remove all sources of ignition. Use personal protective equipment as required.

Most important symptoms and effects, both acute and delayed

Symptoms Potential health effects. 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 over dosage 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 had not been ruled out. Effects of exposure to contents: May cause eye and/or skin irritation. Central nervous system and liver.

Indication of any immediate medical attention and special treatment needed

Note to physicians Cardia 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 a benefit. In limited human overdose experience, seizures and 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. Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use. Dry chemical. Carbon dioxide (CO2). Water spray (fog). Alcohol resistant foam.

Unsuitable extinguishing media Do not use a solid water stream as it may scatter and spread fire.

Specific hazards arising from the chemical

No information available.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters

Wear self contained breathing apparatus for fire fighting if necessary. In the event of fire and/or explosion do not breathe fumes. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Remove all sources of ignition. Evacuate personnel to safe areas. Ensure adequate ventilation, especially in confined areas. Keep people away from and upwind of spill/leak. Use personal protective equipment as required.

Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling	Ensure adequate ventilation, especially in confined areas. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Take precautionary measures against static discharges. Use spark-proof tools and explosion-proof equipment. All equipment used when handling the product must be grounded. Use with local exhaust ventilation. Use personal protective equipment as required. Do not breathe dust/fume/gas/mist/vapors/spray.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep in properly labeled containers. Keep containers tightly closed in a cool, well-ventilated place. Keep away from food, drink and animal feeding stuffs.
Incompatible materials	None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sucrose 57-50-1	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust
Magnesium Stearate 557-04-0	TWA: 10 mg/m ³ except stearates of toxic metals	-	-

NIOSH IDLH *Immediately Dangerous to Life or Health*

Other Information	Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).
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Appropriate engineering controls

Engineering Controls	Ensure adequate ventilation, especially in confined areas.
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Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin and body protection	Wear protective gloves.
Respiratory protection	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

General Hygiene Considerations When using do not eat, drink or smoke. Regular cleaning of equipment, work area and clothing is recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	Odor	Roast Beef and Liver
Appearance	Round Tablet	Odor threshold	No information available
Color	speckled Tan to Brown		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	6.5	
Melting point/freezing point	No information available	
Boiling point / boiling range	No information available	
Flash point	> 36 °C / > 97 °F	Pensky-Martens Closed Cup (PMCC)
Evaporation rate	No information available	
Flammability (solid, gas)	No information available	
Flammability Limit in Air		
Upper flammability limit:	No information available	
Lower flammability limit:	No information available	
Vapor pressure	No information available	
Vapor density	No information available	
Specific Gravity	No information available	
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Partition coefficient	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Oxidizing properties	No information available	

Other Information

Density No information available

10. STABILITY AND REACTIVITY

Reactivity

No data available

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Heat, flames and sparks.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation No data available.

Eye contact Irritating to eyes. Causes serious eye irritation.

Skin Contact Irritating to skin. and. Mucous membrane.

Ingestion No data available.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose 57-50-1	= 29700 mg/kg (Rat)	-	-

Information on toxicological effects

Symptoms No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.
IARC (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans
Not classifiable as a human carcinogen
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

Reproductive toxicity No information available.

STOT - single exposure Respiratory system. Exposure 3.

STOT - repeated exposure No information available.

Chronic toxicity Avoid repeated exposure.

Target Organ Effects Eyes, Respiratory system, Skin.

Aspiration hazard No information available.

Numerical measures of toxicity - Product Information

Unknown Toxicity 26 % of the mixture consists of ingredient(s) of unknown toxicity

Oral LD50 248 mg/kg Mouse

Dermal LD50 > 500 mg/kg (rabbit)

Inhalation LC50 1.57 mg/L Trout

12. ECOLOGICAL INFORMATION

Ecotoxicity

69% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Do not reuse container, unless specified by the manufacturer.

14. TRANSPORT INFORMATION

DOT

Description	Not regulated for transport under DOT regulations. This product does not qualify as a Hazardous Material.
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15. REGULATORY INFORMATION

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

International Inventories

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed
ENCS	Not Listed
IECSC	Not Listed
KECL	Not Listed
PICCS	Not Listed
AICS	Not Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

Chemical Name	TSCA	DSL	NDSL	EINECS	ELINCS	ENCS	IECSC	KECL	PICCS	AICS
Di-Tab (Dibasic Calcium Phosphate Dihydrate)		X					X		X	X
Sucrose	X	X		X			X	X	X	X
Magnesium Stearate	X	X		X		X	X	X	X	X

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	Yes
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Sucrose 57-50-1		X	X

International Regulations

Mexico - Grade

Serious risk, Grade 3

Chemical Name	Carcinogenicity	Exposure Limits
Sucrose		Mexico: TWA 10 mg/m ³ Mexico: STEL 20 mg/m ³

16. OTHER INFORMATION

<u>NFPA</u>	Health hazards 1	Flammability 0	Instability 0	Physical and Chemical Properties -
<u>HMIS</u>	Health hazards 1	Flammability 0	Physical hazards 0	Personal protection X

Disclaimer

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End of Safety Data Sheet