

SAFETY DATA SHEETS

This SDS packet was issued with item:

078933680

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 078933679 078941573 078941575 078941576 078941580 078945672

Issue Date 20-Jul-2017

Revision Date 27-Aug-2020

Version 2

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 90034057
Product Size 8 mg (10034057), 16 mg (10034157), 32 mg (10034257), 64 mg (10034357)
ANADA Number 141-272
NDC Number 49427-340-57

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

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

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

Emergency telephone number

24 Hour Emergency Phone Number 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)

| | |
|--|------------|
| Serious eye damage/eye irritation | Category 1 |
| Specific target organ toxicity (single exposure) | Category 3 |
| Acute Aquatic Toxicity | Category 3 |

Label elements

Emergency Overview

Signal word

Danger

Hazard statements

- Causes serious eye damage
- May cause drowsiness or dizziness
- Harmful to aquatic life



Appearance Round Tablet

Physical state Solid

Odor Liver

Precautionary Statements - Prevention

Wear eye protection/ face protection
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Avoid release to the environment

Precautionary Statements - Response

IF INHALED: Remove person to fresh air and keep comfortable for breathing
Call a POISON CENTER or doctor/physician if you feel unwell
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

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

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

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Read label before use.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Not applicable.

Mixture

| Chemical name | CAS-No | Weight-% |
|----------------------------|------------|----------|
| Microcrystalline Cellulose | 9004-34-6 | 30-40% |
| Sucrose | 57-50-1 | 5-10% |
| Fluoxetine hydrochloride | 59333-67-4 | 2-12% |
| Magnesium Stearate | 557-04-0 | 1.0-2.5% |

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

4. FIRST AID MEASURES

Description of first aid measures

| | |
|-----------------------|---|
| General advice | IF exposed or concerned: Get medical advice/attention. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). |
| Eye contact | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Call a physician. |
| Skin contact | Wash skin with soap and water. If symptoms persist, call a physician. |
| Inhalation | Remove to fresh air. Get medical attention immediately if symptoms occur. |
| Ingestion | Clean mouth with water and drink afterwards plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Call a physician. |

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.

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

Unsuitable extinguishing media No information available.

Specific hazards arising from the chemical In the event of fire and/or explosion do not breathe fumes. Thermal decomposition can lead to release of irritating and toxic gases and vapors. May emit toxic fumes under fire conditions. Carbon oxides. Nitrogen oxides (NOx). Hydrogen chloride. Hydrogen fluoride.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment for fire-fighters 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 Ensure adequate ventilation, especially in confined areas. Wear protective gloves/protective clothing and eye/face protection. Avoid breathing dust/fume/gas/mist/vapors/spray.

Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so Prevent product from entering drains Do not allow into any sewer, on the ground or into any body of water See Section 12 for additional ecological information

Other information Refer to protective measures listed in Sections 7 and 8.

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 Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Use personal protection equipment. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Use in a well-ventilated location. Avoid generation of dust. Avoid breathing dust/fume/gas/mist/vapors/spray.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from sunlight. Keep out of the reach of children. Keep in properly labeled containers. Keep away from food, drink and animal feeding stuffs.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits

| Chemical name | ACGIH TLV | OSHA PEL | NIOSH IDLH |
|---|---|--|--|
| Microcrystalline Cellulose 9004-34-6 | 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 (vacated) TWA: 5 mg/m ³ (vacated) STEL: 10 mg/m ³ | TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust TWA: 1 mg/m ³ |
| 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 inhalable particulate matter TWA: 3 mg/m ³ respirable particulate matter TWA: 10 mg/m ³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m ³ respirable particulate matter except stearates of toxic metals | - | - |

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

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Chemical resistant gloves.

Skin and body protection Wear long-sleeved shirt, long pants, socks and shoes.

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 Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

| | |
|----------------|--------------------------|
| Physical state | Solid |
| Appearance | Round Tablet |
| Color | speckled Tan to Brown |
| Odor | Liver |
| Odor threshold | No information available |

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|-------------------------------|-------------------|-------------------------|
| pH | 6.5 | |
| Melting point/freezing point | | None known |
| Boiling point / boiling range | No data available | None known |
| Flash point | No data available | None known |
| Evaporation rate | No data available | None known |
| Flammability (solid, gas) | No data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability limit: | No data available | |
| Lower flammability limit: | No data available | |
| Vapor pressure | No data available | None known |
| Vapor density | No data available | None known |
| Specific Gravity | No data available | None known |
| Water solubility | Soluble in water | |
| Solubility in other solvents | No data available | None known |
| Partition coefficient | No data available | None known |
| Autoignition temperature | No data available | None known |
| Decomposition temperature | No data available | None known |

Other Information

| | |
|----------------|--------------------------|
| Liquid Density | No information available |
| Bulk density | No information available |

10. STABILITY AND REACTIVITY

Reactivity

No information available.

Stability

Stable under recommended storage conditions

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Keep out of reach of children.

Incompatible materials

Oxidizing agents.

Hazardous decomposition products

May emit toxic fumes under fire conditions. Carbon oxides. Nitrogen oxides (NOx). Hydrogen chloride. Hydrogen fluoride.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

| | |
|-------------|--|
| Inhalation | May cause irritation of respiratory tract. |
| Eye contact | Causes serious eye damage. |

Skin contact May be harmful in contact with skin.

Ingestion May be harmful if swallowed.

Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---|-----------------------|---|--------------------------------------|
| Microcrystalline Cellulose 9004-34-6 | > 5 g/kg (Rat) | > 2 g/kg (Rabbit) > 2000 mg/kg (Rabbit) | > 5800 mg/m ³ (Rat) 4 h |
| Sucrose 57-50-1 | = 29700 mg/kg (Rat) | - | - |
| Fluoxetine hydrochloride 59333-67-4 | (Oral-mice) 248mg/kg | - | - |

Symptoms related to the physical, chemical and toxicological characteristics

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.

Acute toxicity

Numerical measures of toxicity - Product Information

Unknown Toxicity

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

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure May cause drowsiness or dizziness.

STOT - repeated exposure No information available.

Target Organ Effects Eyes, Skin, Respiratory system, Central nervous system, Liver.

12. ECOLOGICAL INFORMATION

Ecotoxicity Harmful to aquatic life.

| Chemical name | Algae/aquatic plants | Fish | Toxicity to | Crustacea |
|---------------|----------------------|------|-------------|-----------|
|---------------|----------------------|------|-------------|-----------|

| | | | microorganisms | |
|--|---|--|----------------|--|
| Fluoxetine hydrochloride 59333-67-4 | - | LC50 (96h): 1.57 mg/l (Oncorhynchus mykiss, rainbow trout) | - | EC50 (48h): 0.94 mg/l (Daphnia magna, water flea) |

Persistence and degradability No information available.

Bioaccumulation No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated

15. REGULATORY INFORMATION

FDA Statement

This chemical is classified as a food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, and is therefore subject to labeling requirements under the Food and Drug Administration. These requirements differ from the classification criteria and hazard information required for safety data sheets and workplace labeling of chemicals.

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

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

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

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

U.S. State Right-to-Know Regulations

US State Regulations

| Chemical name | New Jersey | Massachusetts | Pennsylvania |
|---|------------|---------------|--------------|
| Microcrystalline Cellulose 9004-34-6 | X | X | X |
| Sucrose 57-50-1 | - | X | X |

16. OTHER INFORMATION

| | | | | |
|-----------------------------------|----------------------------------|----------------|--------------------|------------------------------------|
| <u>NFPA</u> | Health hazards 3 | Flammability 1 | Instability 0 | Physical and Chemical Properties - |
| <u>HMIS</u> | Health hazards 3 | Flammability 1 | Physical hazards 0 | Personal protection X |
| <i>Chronic Hazard Star Legend</i> | <i>* = Chronic Health Hazard</i> | | | |

Disclaimer

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End of Safety Data Sheet