



SAFETY DATA SHEET

Revision Date 16-Jul-2019

Version 2

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

Product identifier

Product Name SARAFEM

Other means of identification

Product Code FG00159

Synonyms Fluoxetine Hydrochloride Tablets

Recommended use of the chemical and restrictions on use

Recommended Use Selective Serotonin Re-uptake Inhibitors premenstrual dysphoric disorder (PMDD)

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet

Manufacturer

Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address SDS@Allergan.com

Emergency telephone number

Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

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

Acute toxicity - Oral	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Carcinogenicity	Category 2

Label elements

Emergency Overview

Warning

Hazard statements

H351 - Suspected of causing cancer



Appearance Tablet	Physical state Solid	Odor No information available
Chemical Name Trospium Chloride POVIDONE USP(PLASDONE K-29-32)	Symptoms The most common adverse reactions are dry mouth, constipation, and headache. Possible eye, skin, gastrointestinal and/or respiratory tract irritation. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Overdose effects from ingestion of large amounts include abdominal cramps, flatulence, and fecal impaction.	
Chemical Name Trospium Chloride POVIDONE USP(PLASDONE K-29-32)	Medical Conditions Aggravated by Exposure This medication is contraindicated in patients with: urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, known hypersensitivity to the drug or its ingredients; angioedema, rash and anaphylactic reaction have been reported. Known hypersensitivity to this medication	

Precautionary statements

- P264 - Wash face, hands and any exposed skin thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
- P330 - Rinse mouth
- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P271 - Use only outdoors or in a well-ventilated area
- P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- P312 - Call a POISON CENTER or doctor if you feel unwell
- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P281 - Use personal protective equipment as required
- P308 + P313 - IF exposed or concerned: Get medical advice/attention
- P405 - Store locked up
- P501 - Dispose of contents/ container to an approved waste disposal plant

Other Information

Unknown Acute Toxicity 32.58% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
MICROCRYSTALLINE CELLULO(AVICEL PH102)	9004-34-6	232-674-9	7 - 13*
SILICON DIOXIDE NF(SYLOID 244FP)	7631-86-9	231-545-4	7 - 13*
Trospium Chloride	10405-02-4	233-875-4	1 - 5*
POVIDONE USP(PLASDONE K-29-32)	9003-39-8	N/A	1 - 5*
MAGNESIUM STEARATE NF(VEGETABLE SOURCE)	557-04-0	209-150-3	1 - 5*
TALC USP(1656)	14807-96-6	238-877-9	0.1 - 1*

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

4. FIRST AID MEASURES

First aid measures

General advice	If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing.
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	Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Inhalation	Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Ingestion	Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting.

Chemical Name
Trospium Chloride

Note to physicians

Trospium chloride is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and known hypersensitivity to the drug or its ingredients. Angioedema, rash and anaphylactic reaction have been reported.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

Explosion data

Sensitivity to Mechanical Impact
Sensitivity to Static Discharge

Not impact sensitive.

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

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	Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions	Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. See Section 12 for additional ecological information.
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.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

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	Allergan OEL (ug/m ³)
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 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	N/A
SILICON DIOXIDE NF(SYLOID 244FP) 7631-86-9	N/A	(vacated) TWA: 6 mg/m ³ <1% Crystalline silica TWA: 20 mppcf : (80)/(%) SiO ₂ mg/m ³ TWA	IDLH: 3000 mg/m ³ TWA: 6 mg/m ³	N/A
Trospium Chloride 10405-02-4	N/A	N/A	N/A	100 ug/m ³
MAGNESIUM STEARATE NF(VEGETABLE SOURCE) 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	N/A	N/A	N/A
TALC USP(1656) 14807-96-6	TWA: 2 mg/m ³ particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter	(vacated) TWA: 2 mg/m ³ respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more;use Quartz limit	IDLH: 1000 mg/m ³ TWA: 2 mg/m ³ containing no Asbestos and <1% Quartz respirable dust	N/A

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).

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection	No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.
Skin and body protection	During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).
Respiratory protection	Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	Appearance	Tablet
Color	No information available	Odor	No information available
Odor threshold	No information available		

Property

pH

Melting point/freezing point

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

Flammability Limit in Air

Upper flammability limit:

Lower flammability limit:

Vapor pressure

Vapor density

Specific Gravity

Water solubility

Solubility in other solvents

Partition coefficient

Autoignition temperature

Decomposition temperature

Explosive properties

Oxidizing properties

Values

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

Other Information

Molecular weight

VOC Content (%)

Density

Bulk density

No information available

No information available

No information available

No information available

10. STABILITY AND REACTIVITY

Reactivity

Not defined As Reactive substance

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Aerosol formation.

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

Acute toxicity

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Trospium Chloride	If airborne dusts generated by this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.	Contact with the eyes of airborne dusts generated by this compound may cause mild to moderate irritation, redness, and tearing (mechanical irritation).	In therapeutic use, this compound has caused swelling of the skin, rash and anaphylactic reactions. Angioedema of the face, lips, tongue and/or larynx has been reported with therapeutic use of Trospium. Angioedema associated with upper airway swelling may be life threatening. May cause irritation to skin. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).	If this compound is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
MICROCRYSTALLINE CELLULOSE(AVICEL PH102)	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h
SILICON DIOXIDE NF(SYLOID 244FP)	> 5000 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 2.2 mg/L (Rat) 1 h
Trospium Chloride	= 1510 mg/kg (Rat)	N/A	N/A
POVIDONE USP(PLASDONE K-29-32)	= 100 g/kg (Rat)	N/A	N/A

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

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Trospium Chloride	Not mutagenic in the standard battery of tests.	Animal studies in mice and rats have not shown carcinogenicity.	Studies in rats and rabbits have not shown statistically significant levels of teratogenicity or harm to the fetus.	Detectable amounts of this compound have been identified in the milk of nursing women receiving this drug. Caution should be exercised when taking this compound is administered to nursing women.
POVIDONE USP(PLASDONE K-29-32)	No information available.	Not suspected of being a human carcinogen.	No information available.	No information available

Target Organ Effects

Bladder, Eyes, Respiratory system, Skin.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 32.58% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral) 1413 mg/kg

ATEmix (dermal) 6278 mg/kg
 ATEmix (inhalation-dust/mist) 3.4 mg/l

12. ECOLOGICAL INFORMATION

Ecotoxicity

87.75% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
SILICON DIOXIDE NF(SYLOID 244FP) 7631-86-9	440: 72 h Pseudokirchneriella subcapitata mg/L EC50	5000: 96 h Brachydanio rerio mg/L LC50 static	7600: 48 h Ceriodaphnia dubia mg/L EC50
TALC USP(1656) 14807-96-6	N/A	100: 96 h Brachydanio rerio g/L LC50 semi-static	N/A

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Tropium Chloride 10405-02-4	No information available	No information available	No information available	Log P = 0.70

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. Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

ICAO (air) Not regulated

IATA Not regulated

IMDG Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Not Listed
 DSL/NDSL Not Listed
 EINECS/ELINCS 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

US Federal Regulations

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

Chemical Name	ACGIH	IARC	NTP	OSHA
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 9004-34-6	-	Group 1	Known	X
SILICON DIOXIDE NF(SYLOID 244FP) 7631-86-9	-	Group 3	-	-
POVIDONE USP(PLASDONE K-29-32) 9003-39-8	-	Group 3	-	-
TALC USP(1656) 14807-96-6	-	Group 3	-	X

*IARC (International Agency for Research on Cancer)
 Group 1 - Carcinogenic to Humans
 Not classifiable as a human carcinogen
 NTP (National Toxicology Program)
 Known - Known Carcinogen
 OSHA (Occupational Safety and Health Administration of the US Department of Labor)
 X - Present*

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	No
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

Chemical Name	California Proposition 65
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) - 9004-34-6	Carcinogen

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 9004-34-6	X	X	X
TALC USP(1656) 14807-96-6	X	X	X
CORN STARCH NF 9005-25-8	-	X	X

White Cresin Wax 8002-74-2	X	X	X
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16. OTHER INFORMATION

Revision Date 16-Jul-2019
Revision Note No information available

Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet