



# SAFETY DATA SHEET

Revision Date 07-Nov-2019

Version 12

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

### Product identifier

**Product Name** Sucralfate Tablets

### Other means of identification

**Product Code** FG00103

**Synonyms** Carafate Sulcrate

### Recommended use of the chemical and restrictions on use

**Recommended Use** Gastro-Duodenal Cytoprotective Agent

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 not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

### Label elements

#### **Emergency Overview**

The product contains no substances which at their given concentration, are considered to be hazardous to health

**Appearance** Tablet

**Physical state** Solid

**Odor** No information available

#### **Chemical Name**

**Sucralfate**

#### **Symptoms**

The main complaint has been constipation ranging from 1.7% to 3.3% of patients. Other side effects reported included diarrhea, nausea, gastric discomfort, indigestion, dry mouth, back pain, dizziness, sleepiness and vertigo. Cases of hypersensitivity have been reported with the use of sucralfate, including anaphylactic reactions, bronchospasm, dyspnoea, laryngeal oedema, lip swelling, oedema mouth, pharyngeal

	oedema, pruritus, rash, respiratory tract oedema, swelling face and urticarial.
<b>Chemical Name</b> Sucralfate	<b>Medical Conditions Aggravated by Exposure</b> Hypersensitivity to the material. It is recommended to separate the administration of any drug from that of sucralfate when the potential for altered bioavailability is felt to be critical to the effectiveness of that drug. Repeated or prolonged exposure may aggravate medical conditions in immunocompromised individuals.

**Other Information**

Unknown Acute Toxicity 10% 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-%
Sucralfate	54182-58-0	259-018-4	40 - 70*
carboxymethylcellulose sodium	9004-32-4	N/A	10 - 30*
MICROCRYSTALLINE CELLULOSE(AVICEL PH102)	9004-34-6	232-674-9	5 - 10*
Tropium Chloride	10405-02-4	233-875-4	0.1 - 1*
POVIDONE USP(PLASDONE K-29-32)	9003-39-8	N/A	<0.1*

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

### 4. FIRST AID MEASURES

**First aid measures**

<b>Eye contact</b>	Rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	Consult a physician if necessary.

**Chemical Name**  
Sucralfate

**Note to physicians**

Overdosage has never been observed with SULCRATE® (sucralfate) and appears to be unlikely since, using maximal doses of up to 12 g/kg/body weight in a variety of animal species, a lethal dose could not be established. Overdosage is likely to be associated with symptoms similar to those described in the ADVERSE REACTION section, such as constipation. These should be treated symptomatically.

### 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**

Not impact sensitive.

**Sensitivity to Static Discharge**

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**

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. Avoid generation of dust. Do not eat, drink or smoke when using this product.

**Storage Conditions**

Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

**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 <sup>3</sup> )
Sucralfate 54182-58-0	N/A	N/A	N/A	1000
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 9004-34-6	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 5 mg/m <sup>3</sup> (vacated) STEL: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust TWA: 1 mg/m <sup>3</sup>	N/A
Trosium Chloride 10405-02-4	N/A	N/A	N/A	100 ug/m <sup>3</sup>

*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**

<b>Eye/face protection</b>	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.
<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	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

<b>Physical state</b>	Solid	<b>Appearance</b>	Tablet
<b>Color</b>	No information available	<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available		

Property	Values
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
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	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information

<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Density</b>	No information available
<b>Bulk density</b>	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
Tropium 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 Tropium. 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
Sucralfate	> 12 g/kg ( Rat )	N/A	N/A
carboxymethylcellulose sodium	= 27000 mg/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h
MICROCRYSTALLINE CELLULOSE(AVICEL PH102)	> 5 g/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h
Tropium 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
Sucralfate	No information available.	Animal studies in mice, rats and dogs have not shown carcinogenic potential.	Reproduction and teratological studies with sucralfate doses up to 4 g/kg/day body weight in mice and rats and up to 1000 mg/kg of body weight in rabbits did not demonstrate any teratogenic or other associated abnormalities. No deleterious drug-associated effects were seen in terms of general reproductive performance, fertility or perinatal/post-natal	No information available

			responses. The drug levels employed represented doses ranging from 15 to 45 times those recommended in humans.	
Tropium 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** Eyes, Respiratory system, Skin, Gastrointestinal tract (GI).

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity** 10% 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) 11914 mg/kg
- ATEmix (dermal) 6192 mg/kg
- ATEmix (inhalation-dust/mist) 57.4 mg/l

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

99.85% of the mixture consists of components(s) of unknown hazards to the aquatic environment

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
POVIDONE USP(PLASDONE K-29-32) 9003-39-8	-	Group 3	-	-

*IARC (International Agency for Research on Cancer)  
 Group 1 - Carcinogenic to Humans  
 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 does not contain any Proposition 65 chemicals

**U.S. State Right-to-Know Regulations**

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Chemical Name	New Jersey	Massachusetts	Pennsylvania
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	X	X	X
FERRIC OXIDE NF (RED 30) 1309-37-1	X	X	X
CORN STARCH NF 9005-25-8	-	X	X
White Cresin Wax 8002-74-2	X	X	X

**16. OTHER INFORMATION**

**Revision Date** 07-Nov-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**