SAFETY DATA SHEET

Revision Date 02-Oct-2018 **Version** 11

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

Product identifier
Product Name Sucralfate Suspension

Other means of identification
Product Code FG00104
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)

Label elements

Emergency Overview

Appearance Liquid **Physical state** Liquid **Odor** No information available

Chemical Name	Symptoms
GLYCERINE USP (96%)	Adverse effects following oral administration of glycerin include mild headache, dizziness, nausea, vomiting, thirst, and diarrhea.
Sucralfate	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.

Chemical Name	Medical Conditions Aggravated by Exposure
Sucralfate	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 15% 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-%
GLYCERINE USP (96%)	56-81-5	200-289-5	30 - 60*
Sucralfate	54182-58-0	259-018-4	10 - 30*
PROPYLPARABEN NF	94-13-3	202-307-7	7 - 13*
METHYLPARABEN NF	99-76-3	202-785-7	7 - 13*
Dibasic Sodium PhosphateAnhydrous, USP	7558-79-4	231-448-7	3 - 7*

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

4. FIRST AID MEASURES

First aid measures

Eye contact Rinse immediately with plenty of water and seek medical advice.

Skin Contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation Remove to fresh air.

Ingestion Consult a physician if necessary.

Chemical Name	Note to physicians
GLYCERINE USP (96%)	Risk-benefit should be considered when the following medical problems exist: Cardiac disease or hypervolemia (sudden expansion of extracellular fluid may lead to congestive heart failure); Confused mental states or severe dehydration; diabetes mellitus (existing dehydration may affect patient); Renal disease (accumulation may lead to overexpansion of extracellular fluid and circulatory overload).
Sucralfate	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 Avoid creating dust.

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/m³)
GLYCERINE USP (96%) 56-81-5	N/A	TWA: 15 mg/m³ mist, total particulate TWA: 5 mg/m³ mist, respirable fraction (vacated) TWA: 10 mg/m³ mist, total particulate (vacated) TWA: 5 mg/m³ mist, respirable fraction	N/A	N/A
Sucralfate 54182-58-0	N/A	N/A	N/A	1000

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	Liquid	**Appearance**	Liquid
Color	No information available	**Odor**	No information available
Odor threshold	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

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	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	Oral LD50	Dermal LD50	Inhalation LC50
GLYCERINE USP (96%)	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 570 mg/m³ (Rat) 1 h
Sucralfate	> 12 g/kg (Rat)	N/A	N/A
METHYLPARABEN NF	= 2100 mg/kg (Rat)	N/A	N/A
Dibasic Sodium PhosphateAnhydrous, USP	= 17 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
GLYCERINE USP (96%)	Not mutagenic in the standard battery of tests.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	This product does not contain any known or suspected reproductive hazards.	It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.
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 responses. The drug levels employed represented doses ranging from 15 to 45 times those recommended in humans.	No information available

Target Organ Effects Gastrointestinal tract (GI).

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 15% 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) 7952 mg/kg

ATEmix (dermal) 17017 mg/kg

ATEmix (inhalation-dust/mist) 0.2 mg/l

12. ECOLOGICAL INFORMATION

Ecotoxicity

50% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
GLYCERINE USP (96%) 56-81-5	N/A	51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static	500: 24 h Daphnia magna mg/L EC50

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
GLYCERINE USP (96%) 56-81-5	N/A	N/A	N/A	-1.76

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	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

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 contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Dibasic Sodium PhosphateAnhydrous, USP 7558-79-4	5000 lb	-	-	X

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Dibasic Sodium PhosphateAnhydrous, USP 7558-79-4	5000 lb	-	RQ 5000 lb final RQ RQ 2270 kg final RQ

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
GLYCERINE USP (96%) 56-81-5	X	X	X
Dibasic Sodium PhosphateAnhydrous, USP 7558-79-4	X	X	X

16. OTHER INFORMATION

Revision Date 02-Oct-2018

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