

Issuing date: 03/17/2015

Revision date: 05/23/2018

Revision number: 01

1. Identification of the substance/preparation and the company/undertaking

GHS product identifier

Product name: Sucralfate Oral Suspension

Other means of identification

Product code(s): 0121-0747-10; 0121-0747-40
UN-Number: NA

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as a short term treatment of active duodenal ulcer.
Uses advised against: Do not exceed recommended amount per labeled directions or as directed by a physician.

Supplier address/information

Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

2. Hazards Identification

Classification This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical family: Mixture

Statement of Hazard: The product is a pharmaceutical prescription product, and is generally safe when used as directed.

Additional Hazard Information

Short term: The most common adverse effect seen is constipation.

Long term: Sucralfate is intended for short term use (up to eight weeks). Adverse reactions to the drug may include hypersensitivity reactions.

Known Clinical Effects: None known

EU Indication of danger: Not classified

Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

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General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Not expected to be a skin irritant.

Inhalation: Not expected to present a hazard under normal use.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention or contact poison control.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

3. Composition/Information on ingredients

Chemical name	CAS-No	g/10mL	Trade Secret
Sucralfate	54182-58-0	1g/10mL	
Colloidal Silicon Dioxide	7631-86-9		X
Glycerin	56-81-5		X
Methylcellulose	9004-67-5		X
Methylparaben	99-76-3		X
Microcrystalline Cellulose	9004-34-6		X
Simethicone	8050-81-5		X
Sorbitol Solution	Mixture		X
FD&C Red No. 40	25956-17-6		X
Flavor	Mixture		X

4. First aid measures

Description of necessary first-aid measures

Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

Skin contact:

Wash contaminated area thoroughly with soap and water. If irritation persists, contact medical personnel.

Inhalation:

If small amounts of product are inhaled, no specific treatment is necessary since this product is not likely hazardous by inhalation. If exposed to excessive levels, remove to fresh air and get medical attention if cough or symptoms develop.

Ingestion:

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Overdosage or accidental ingestion – Contact medical personnel or poison control center.

Most important symptoms/effects, acute and delayed

No data available.

Indication of immediate medical attention and special treatment needed, if necessary

No data available.

Notes to Physician: NA

5. Fire-fighting measures

Suitable extinguishing media:

Use carbon dioxide, dry chemical or water spray. The product is not expected to be flammable.

Specific hazards arising from the chemical

None.

Explosion data:

Not applicable

Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up

- Methods for containment:
- Methods for cleaning up:

Isolate area around spill as specified by site procedures. Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

7. Handling and storage

Precautions for safe handling

Handling:

No special handling required for hazard control under conditions of normal product use.

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Conditions for safe storage, including any incompatibilities

Storage: No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products: As a precautionary measure, keep away from strong oxidizers.

8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sucralfate	Not Available	Not Available	Not Available
Colloidal Silicon Dioxide	Not Available	80 mg/m ³ TWA	6 mg/m ³
Glycerin	10 mg/m ³ TWA	10 mg/m ³ TWA	Not Available
Methylcellulose	Not Available	Not Available	Not Available
Methylparaben	Not Available	Not Available	Not Available
Microcrystalline Cellulose	10 mg/m ³ TWA	5 mg/m ³ TWA	5 mg/m ³ TWA
Simethicone	Not Available	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
FD&C Red No. 40	Not Available	Not Available	Not Available
Flavor	Not Available	Not Available	Not Available

Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure.

Individual protection measures, such as personal protective equipment

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection: Not required under normal use of the product.

Hygiene measures: Wash hands thoroughly after use.

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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Suspension
 Odor: Faint
 Appearance: Pale Pink suspension
 Odor threshold: Not available

Property	Values	Remarks/Method
pH	3.7 – 4.8	Current USP
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	1.1	Current USP
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information VOC content (%) NA

10. Stability and reactivity

Reactivity Stable at normal conditions

Chemical stability Stable at normal conditions

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Possibility of hazardous reactions Stable at normal conditions

Conditions to avoid None known

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

Hazardous decomposition products None known

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Sucralfate	>8000 mg/kg Mouse	Not Available	Not Available
Colloidal Silicon Dioxide	3160 mg/kg rat	>2000 mg/kg Rabbit	>2.2 mg/L 1 hr. Rat
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
Methylcellulose	Not Available	Not Available	Not Available
Methylparaben	2100 mg/kg Rat	No skin irritation 24 hr. Rabbit	Not Available
Microcrystalline Cellulose	>5000 mg/kg Rat	>2000 mg/kg Rabbit	Not Available
Simethicone	>5000 mg/kg (No species given)	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
FD&C Red No. 40	>10000mg/kg Rat	>10000 mg/kg Rabbit	Not Available
Flavor	Not Available	Not Available	Not Available

Symptoms related to the physical, chemical and toxicological characteristics

No data available

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Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

Numerical measures of toxicity – product

- No data available

12. Ecological information

Ecotoxicity:

Environmental properties have not been thoroughly evaluated for the product. Releases to the environment should be avoided.

Persistence and Degradability

No data available

Bioaccumulation

No data available

Other adverse effects:

No data available.

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Sucralfate	Not Available	Not Available	Not Available	Not Available
Colloidal Silicon Dioxide	440 mg/L 72 hr. Pseudokirchneriella subcapitata	5000 mg/L 96 hr. Brachydanio rerio	Not Available	7600 mg/L 48 hr.
Glycerin	Not Available	58.5 ppm 96 hr. Trout	Not Available	Not Available
Methylcellulose	Not Available	>1000 mg/L 48 hr. Oryzias latipes	Not Available	Not Available
Methylparaben	91 mg/L 72 hr. Pseudokirchneriella subcapitata	59.5 mg/L 89 hr. Oryzias latipes	Not Available	41.1 mg/L 48 hr.
Microcrystalline Cellulose	Not Available	Not Available	Not Available	Not Available
Simethicone	Not Available	Not Available	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available	Not Available
FD&C Red No. 40	Not Available	Not Available	Not Available	Not Available
Flavor	Not Available	Not Available	Not Available	Not Available

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13. Disposal considerations

Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

14. Transport information

Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

15. Regulatory information

International inventories

EINECS:

Sucralfate, Colloidal Silicon Dioxide, Glycerin, Methylparaben, Methylcellulose, Microcrystalline Cellulose, and FD&C Red No. 40 are included on the inventory.

Legend

TSCA:

United States Toxic Substances Control Act 8(b) inventory not applicable for product. The following components are included on the inventory: Colloidal Silicon Dioxide, Glycerin, Methylparaben, Methylcellulose, Microcrystalline Cellulose, and FD&C Red No. 40

U.S. Federal regulations:

Not Applicable

SARA 311/312 Hazard categories:

Not Applicable

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:

No components are listed under CERCLA

California Proposition 65:

This product does not contain any ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute.

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U.S. state Right-to-Know regulations

“X” designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Sucralfate	X		X		
Colloidal Silicon Dioxide	X	X	X		
Glycerin	X	X	X	X	X
Methylcellulose	X		X		
Methylparaben	X		X		
Microcrystalline Cellulose	X	X	X		
Simethicone	X				
Sorbitol Solution	X		X		
FD&C Red No. 40 Flavor					

U.S. EPA label information:

Not applicable

16. Other information

Prepared by:

Issuing date:

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Revision note:

Pharmaceutical Associates Regulatory Affairs Department

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Rev 01:

- Changed Product Name from Sucralfate Suspension to Sucralfate Oral Suspension
- Added NDC 0121-0747-40
- Remove reference to synonym

General Disclaimer

The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet