SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

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

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: C**arafate Suspension**

DESCRIPTION: Carafate Suspension
RELEVANT USE of the SUBSTANCE: Human Pharmaceutical/Anti-Inflammatory
USES ADVISED AGAINST: Non-Pharmaceutical Use
CHEMICAL NAME: For Active Ingredient: 5-amino-2-hydroxybenzoic acid
CHEMICAL FAMILY: For Active Ingredient: Aminosalicylate
FORMULA: For Active Ingredient: $C_7H_7NO_3$
HOW SUPPLIED: 1000 mg Solution

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:	**Actavis, Inc.**
U.S. ADDRESS:	400 Interpace Parkway, Morris Corporate Center III Parsippany, NJ 07054, USA
U.S. BUSINESS PHONE/GENERAL SDS INFORMATION:	1-800-272-5525
RESPONSIBLE PARTY EUROPE:	
EUROPEAN ADDRESS:	
EUROPEAN BUSINESS PHONE:	
EMERGENCY PHONE (U.S./NORTH AMERICA):	CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico
EMERGENCY PHONE (OUTSIDE U.S.):	CHEMTREC: +1-703-527-3887 (24 hours) Outside North America
Email:	SDS@Actavis.com

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: January 19, 2015 **DATE OF REVISION:** New

2. HAZARDS IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW:

Product Description: This product is supplied as a pink liquid suspension.

Health Hazards: Accidental ingestion may be harmful. In therapeutic use, the most common adverse effect reported has been constipation. Therapeutic use may cause adverse effects to the skin, central nervous and gastrointestinal systems. Serious hypersensitivity reactions have been reported, including anaphylactic reactions. More information on adverse effects from therapeutic use is described in Section 11 (Toxicological Information).

Flammability Hazards: This product is combustible and may ignite if exposed to high temperature for a prolonged period. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including aluminum, carbon, silicon and nitrogen oxides and acrolein).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Other Hazards: No other hazard information currently known.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
ACTIVE INGREDIENT:				
Sucralfate α-D-glucopyranoside, β-D-fructofuranosyl-, octakis(hydrogen sulfate), aluminum complex	54182-580	259-018-4	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable

See Section 15 for full classification.

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
EXCIPIENTS:				
Colloidal Silicon Dioxide	112926-00-8	Not Listed	Proprietary	SELF-CLASSIFICATION EU 67/548 Classification: Not Applicable GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: Not Applicable
FD&C Red No. 40	4548-53-2	224-909-9	Proprietary	SELF CLASSIFICATION EU (67/548/EEC): Classification: Harmful Risk Phrases: R22 EU/GHS 1272/2008: Classification: Acute Oral Toxicity Cat. 4 Hazard Statement Codes: H302 Hazard Symbols/Pictograms: GHS07
Flavor	Mixture	Mixture	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Glycerin	56-81-5	200-289-5	Proprietary	SELF-CLASSIFICATION: EU (67/548/EEC): Classification: Not Applicable EU/GHS 1272/2008: Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303 Hazard Symbols/Pictograms: None Applicable
Methyl Paraben	99-76-3	202-785-7	Proprietary	SELF CLASSIFICATION EU (67/548/EEC): Classification: Not Applicable EU/GHS 1272/2008: Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303 Hazard Symbols/Pictograms: None Applicable
Methyl Cellulose	9004-67-5	Not Listed	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Microcrystalline Cellulose NF	9004-34-7	Not Listed	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Simethicone	8050-81-5	Not Listed	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Sorbitol	50-70-4	200-061-5	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Water	7732-18-5	231-791-2	Balance	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable

See Section 15 for full classification.

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Upon contact of this material with skin, eyes, or mucous membranes, immediately decontaminate by flushing with water for at least 20 minutes. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

Inhalation: If this product is inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

Skin Exposure: Basic hygiene should prevent any problems. If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

Eye Exposure: If this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

Ingestion Exposure: If this product 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.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, pre-existing renal impairment, conditions that may impair swallowing, such as recent or prolonged intubation, tracheostomy, prior history of aspiration, dysphagia, or any other conditions that may alter gag and cough reflexes, or diminish oropharyngeal coordination or motility may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to components or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

4 FIRST-AID MEASURES (Continued)

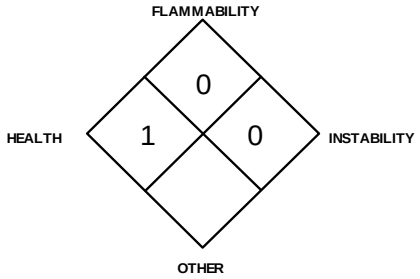
IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive immediate medical attention. There is no specific antidote for this product. Treatment should be symptomatic and supportive.

5. FIRE-FIGHTING MEASURES

FLASHPOINT: Not applicable.
AUTOIGNITION TEMPERATURE: Not applicable.
FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): Not applicable.
FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.
UNSUITABLE EXTINGUISHING MEDIA: None known.
SPECIFIC HAZARDS ARISING FROM THE PRODUCT: This product is not combustible and may ignite if exposed to high temperature for a prolonged period. If involved in a fire, the water component may evaporate and the residual may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including aluminum, carbon, silicon and nitrogen oxides and acrolein).

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** =

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Monitor area and confirm levels are bellow exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g., several bottles), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., 1 liter or more), protective apparel should be used with a respirator when there is any danger of aerosols being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be **Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.**

METHODS FOR CLEANUP AND CONTAINMENT:

Small Spills: Absorb up spilled material with damp sponge, polypads or other suitable material.

Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Absorb spilled product carefully, avoiding the generation of aerosols onto polypads or other non-reactive absorption.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

7. HANDLING and USE

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be trained to handle it safely. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product or equipment and containers that contain this product. Do not eat or drink while using this product. Avoid breathing airborne mists or spray generated by this product. Ensure this product is used with adequate ventilation (refer to Section 8, Exposure Controls-Personal Protection). Remove contaminated clothing immediately. Keep container tightly closed when not in use. Open containers slowly on a stable surface in areas that have been designated for use of this product. Wipe down areas in which this product is used, so that product does not accumulate. Empty containers may contain residual material; therefore, empty containers should be handled with care.

7. HANDLING and USE (Continued)

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight, sources of intense heat or other sources of ignition or where freezing is possible. Store at 20-25°C (68-77°F) and away from moisture, humidity and light. Product should be stored in secondary containers or in a diked area, as appropriate. Store away from incompatible materials (see Section 10, Stability and Reactivity).

SPECIFIC END USE(S): This product is a human pharmaceutical. Follow all industry standards for use of this product.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Occupational/Workplace Exposure Limits/Guidelines:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Sucralfate	54182-58-0	NE	NE	NE	NE	NE	NE	NE	Actavis WEL: 1000 $\mu g/m^3$
Colloidal Silicon Dioxide	112926-00-8	NE	NE	20 mppcf or	$\frac{80\ mg/m^3}{\%\ SO_2}$	6 See NIOSH Pocket Guide App. C		3000	Carcinogen: IARC-3, TLV-A3
FD&C Red No. 40	4548-53-2	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Glycerin	56-81-5	NE	NE	15 (total dust) 5 (resp. fract.) 10 (total) 5 (resp. fract.) [vacated 1989 PEL]	NE	NE	NE	NE	DFG MAKs: TWA = 50 (Inhalable fraction) PEAK = 2•MAK 15 min, average value, 1-hr interval, 4 per shift Pregnancy Risk Classification: C
Methylcellulose Exposure limits are for cellulose	9004-67-5	10	NE	15 (total dust), 5 (resp. fract.)	10 (total dust), 5 (resp. fract.)	NE	NE	NE	NE
Methyl Paraben	99-76-3	NE	NE	NE	NE	NE	NE	NE	NE
Propyl Paraben	94-13-3	NE	NE	NE	NE	NE	NE	NE	NE
Simethicone	8050-81-5	NE	NE	NE	NE	NE	NE	NE	NE
Sorbitol	50-70-0	NE	NE	NE	NE	NE	NE	NE	NE
Water, Purified	7732-18-5	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established.

International Occupational Exposure Limits: Currently, THE additional exposure limits have been established by various countries for components of this product. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.

SUCRALFATE:
Korea: TWA = 2 mg(Al)/m3, 2006
New Zealand: TWA = 2 mg(Al)/m^3, JAN 2002
Russia: STEL = 2 mg/m^3, JUN 2003

COLLOIDAL SILICON DIOXIDE:
Australia: TWA = 2 mg/m^3 (respirable dust), JUL 2008
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

GLYCERIN:
Belgium: TWA = 10 mg/m^3, MAR 2002
Finland: TWA = 20 mg/m^3, NOV 2011
France: VME = 10 mg/m^3, FEB 2006
Germany: MAK = 50 mg/m^3, inhal, 2011
Korea: TWA = 10 mg/m^3 (mist), 2006
Mexico: TWA = 10 mg/m^3 (inhalable), 2004

GLYCERIN (continued):
The Netherlands: MAC-TGG = 10 mg/m^3, 2003
New Zealand: TWA = 10 mg/m^3 (mist), JAN 2002
Peru: TWA = 10 mg/m^3, JUL 2005
Switzerland: MAK-W = 50 mg/m^3, KZG-W = 100 mg/m^3, inhal, JAN 2011
United Kingdom: TWA = 10 mg/m^3, OCT2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

METHYL CELLULOSE:
Russia: STEL = 10 mg/m^3, JUN 2003

METHYL PARABEN:
Russia: STEL = 4 mg/m^3, JUN 2003

PROPYL PARABEN:
Russia: STEL = 10 mg/m^3, JUN 2003

SORBITOL:
Russia: STEL = 10 mg/m^3, JUN 2003

PERSONAL PROTECTIVE EQUIPMENT: Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

Respiratory Protection: A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

Eye Protection: During operations in which mists or sprays may be generated, splash goggles or safety glasses should be considered.

Hand Protection: During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

Body Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.).

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product.

FORM: Liquid.
COLOR: As described in Section 2.
ODOR: No odor.
ODOR THRESHOLD: Not available.
HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product is a distinguishing characteristic.

The following information is for the Sucralfate active ingredient.

FORM: Amorphous powdered solid.
COLOR: White.
MOLECULAR WEIGHT: 1448.68
MOLECULAR FORMULA: $C_{11}H_{28}Al_8O_5S_8$
ODOR: Odorless.
ODOR THRESHOLD: Odorless.
MELTING POINT: Not available.
pH: Not available.
VAPOR PRESSURE (air = 1) @ 25°C: 0 Not available.
SPECIFIC GRAVITY (water = 1): Not available.
EVAPORATION RATE (nBuAc = 1): Not applicable.
FLASH POINT: Not available.
SOLUBILITY IN WATER: Practically insoluble.
BOILING POINT @ 760 mmHg: Not available.
OTHER SOLUBILITIES: Soluble in dilute hydrochloric acid and sodium hydroxide solution. Practically insoluble in ethanol, chloroform.
COEFFICIENT WATER/OIL DISTRIBUTION: Not available.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable under normal conditions of storage.
HAZARDOUS DECOMPOSITION PRODUCTS: ***Combustion:*** If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., aluminum, carbon and nitrogen oxides and acrolein). ***Hydrolysis:*** None known.
INCOMPATIBLE MATERIALS: This compound is incompatible with strong oxidizers, strong acids.
POSSIBILITY OF HAZARDOUS REACTIONS/ POLYMERIZATION: No data available.
CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to employee handling in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Inhalation of airborne aerosols generated by this product may irritate the nose, throat, and lungs.
Skin Contact: Contact with the skin may cause irritation. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).
Eye Contact: Contact with the eyes of aerosols generated by this product may cause irritation, redness, and tearing.
Skin Absorption: No specific data is available on potential absorption of this product through intact skin.
Ingestion: Accidental ingestion of this product (i.e., through poor hygiene practices) may be harmful. Acute oral toxicity studies in animals, however, using doses up to 12 g/kg body weight, could not find a lethal dose. Sucralfate is only minimally absorbed from the gastrointestinal tract. Other effects may occur as described under 'Other Potential Health Effects'.
Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may also include those described under 'Other Health Effects'.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	1
FLAMMABILITY HAZARD	(RED)	0
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe * = Chronic hazard

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, the most common adverse effect reported has been constipation. Therapeutic use may cause adverse effects to the skin, central nervous and gastrointestinal systems. Serious hypersensitivity reactions have been reported, including anaphylactic reactions. In therapeutic use the following additional adverse effects described by body system have included:

- ***Central Nervous System:*** Dizziness, insomnia, sleepiness, vertigo, headache.
- ***Gastrointestinal System:*** Diarrhea, nausea, vomiting, gastric discomfort, indigestion, flatulence, dry mouth, development of a solid mass of indigestible material.
- ***Hypersensitivity Reactions:*** Anaphylaxis, difficulty breathing, lip swelling, itching, rash, and hives, anaphylactic reactions, bronchospasm, swelling of the larynx, pharynx, respiratory tract.
- ***Musculoskeletal System:*** Back pain.
- ***Respiratory System:*** Bronchospasm, interstitial pneumonia.
- ***Skin:*** Itching, rash.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: May be harmful by accidental ingestion. Prolonged contact with this product may cause irritation via skin or eye contact.

11. TOXICOLOGICAL INFORMATION (Continued)

HEALTH EFFECTS OR RISKS FROM EXPOSURE (continued):

Chronic: Repeated skin contact may cause dermatitis (dry, red skin). Chronic exposure may cause adverse symptoms as described under 'Other Health Effects'.

TARGET ORGANS: It is anticipated that for Occupational Exposure the target organs are: **Acute:** Gastrointestinal system. **Chronic:** In therapeutic use this material may have an impact on the body systems described under 'Other Potential Health Effects'.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue if contact is prolonged.

SENSITIZATION TO THE PRODUCT: In therapeutic use, anaphylaxis, difficulty breathing, lip swelling, itching, rash, and hives, anaphylactic reactions, bronchospasm, swelling of the larynx, pharynx, and respiratory tract have been reported.

TOXICITY DATA: Currently the following toxicity data are available for the active ingredient. Additional data are available, for excipients, but are not presented in this SDS. Contact Actavis for more information.

SULCRAFATE:

TDLo (Oral-Human) 20 mg/kg/10 minutes: Immunological Including Allergic: anaphylaxis

TDLo (Oral-Infant) 1276 mg/kg/3 days-intermittent: Cardiac: pulse rate

LD_{50} (Oral-Rat) > 12 gm/kg

LD_{50} (Oral-Mouse) > 8 gm/kg

SULCRAFATE (continued):

LD_{50} (Intraperitoneal-Rat) >4 gm/kg

LD_{50} (Intraperitoneal-Mouse) >8 gm/kg

LD_{50} (Subcutaneous-Rat) >4 gm/kg

LD_{50} (Subcutaneous-Mouse) >8 gm/kg

CARCINOGENIC POTENTIAL OF COMPONENTS: The following information is available for the active ingredient.

Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 g/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. This material is not listed by agencies tracking the carcinogenic potential of chemical compounds.

The excipient components are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

COLLOIDAL SILICON DIOXIDE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Human Carcinogenicity)

FD&C RED NO. 40: IARC-3 (Unclassifiable as to Human Carcinogenicity)

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of Sucralfate in pregnant women; however, when administered therapeutically, Sucralfate is not expected to cause fetal harm when administered to a pregnant woman. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category B (Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester).

Mutagenicity: Mutagenicity studies were not conducted.

Embryotoxicity/Teratogenicity: Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to Sucralfate.

Reproductive Toxicity: A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. It is not known if Sucralfate is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY IN SOIL: This product has not been tested for mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIO-ACCUMULATIVE POTENTIAL: This product is not expected to present a hazard of bioconcentration.

ECOTOXICITY: No data is available for this product. All releases to terrestrial, atmospheric and aquatic environments should be avoided.

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

OTHER ADVERSE EFFECTS: This material has no known ozone depletion potential.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. Waste containers should be handled with uncontaminated gloves. Reusable equipment should be decontaminated using 0.05M Boric acid solution adjusted to pH 9 with 10 N sodium hydroxide followed by a detergent wash and then clean water rinse or by using a bleach solution (triple wash) and a detergent solution followed by clean water rinse.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

13. DISPOSAL CONSIDERATIONS (Continued)

U.S. EPA WASTE NUMBER: Not applicable.

EUROPEAN WASTE CODES: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA: This product is NOT classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO): This product is NOT classified as Dangerous Goods, per rules of IMO.

UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE (UNECE): This product is NOT classified by the United Nations Economic Commission for Europe to be dangerous goods.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product is neither environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) nor a marine pollutant according to the IMDG Code and is not listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

Other U.S. Federal Regulations: Regulations of the FDA under the Federal Food, Drug and Cosmetic Act are applicable when this material is used in pharmaceutical preparations. Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component of this product is on the California Proposition 65 Lists.

CANADIAN REGULATIONS:

Canadian DSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: The components of this product are not on the CEPA Priorities Substances Lists.

Canadian WHMIS Classification and Symbol: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: When formulated in a finished medicinal product for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

U.S. ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! ACCIDENTAL INGESTION MAY BE HARMFUL. MAY CAUSE SERIOUS ALLERGIC REACTIONS IN SUSCEPTIBLE INDIVIDUALS. Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting. Seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Absorb spilled product with appropriate materials/absorbent. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

16. OTHER INFORMATION (Continued)

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Colloidal Silicon Dioxide. Glycerin, Methyl Paraben: This is a self-classification.
Classification: Acute Oral Toxicity Category 5
Hazard Statements: H303: May be harmful if ingested.

FD&C Red No. 40: This is a self-classification.
Classification: Acute Oral Toxicity Category 4
Hazard Statements: H302: Harmful if swallowed.

Other Components: An official classification for these substances has not been published nor is applicable.

67/548/EEC:

FD&C Red No. 40: This is a self-classification.
Classification: Harmful
Risk Phrases: R22: Harmful if swallowed.

Other Components: An official classification for these substances has not been published nor is applicable.

REFERENCES AND DATA SOURCES: Contact the supplier for information.
METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.
REVISION DETAILS: New.
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