



Actavis

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: CARAFATE® (Sucralfate) TABLET

DESCRIPTION: Sucralfate Tablets

CHEMICAL NAME: For Active Ingredient: α-D-glucopyranoside, β-D-fructofuranosyl-, octakis(hydrogen sulfate), aluminum complex

CHEMICAL FAMILY: For Active Ingredient: Organooxygen Disaccharide

FORMULA: For Active Ingredient: C₁₁H₂₈Al₈O₅₁S₈

RELEVANT USE of the SUBSTANCE: Human Pharmaceutical / Anti-Ulcer Agent

USES ADVISED AGAINST: Non-Pharmaceutical Use

HOW SUPPLIED: 1 g Light Pink Oblong Tablets: NDC 58914-171-10: in bottles of 100

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: August 30, 2014

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 light pink oblong tablets.

Health Hazards: In the workplace, exposure to dusts from product via inhalation and skin contact may cause irritation. Eye contact from dusts can cause mechanical irritation. 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. Other adverse effects seen from therapeutic use are described in Section 11 (Toxicological information).

Flammability Hazards: If heated to high temperatures for a prolonged period, the product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including aluminum, carbon, sulfur and magnesium oxides).

Reactivity Hazards: This product is not reactive.

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

Emergency Considerations: Emergency responders should wear appropriate protection for the 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
ACTIVE INGREDIENT				
Sucralfate α-D-glucopyranoside, β-D-fructofuranosyl-, octakis(hydrogen sulfate), aluminum complex	54182-580	259-018-4	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.

See Section 16 for full classification information.

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
EXCIPIENTS				
Corn Starch	9005-25-8	232-679-6	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
D&C Red No. 40 Aluminum Lake	1342-90-1	Not Listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
FD&C Blue No. 1 Lake	68921-42-6	272-939-6	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Magnesium Stearate	557-04-0	209-150-3	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Microcrystalline Cellulose	9004-34-6	232-674-9	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.

See Section 16 for full classification information.

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: Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of label and SDS to physician or other health professional with victim(s).

Inhalation: If dusts or particulates from this product are 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: 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 particulates from this product enter 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.

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, pre-existing 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.

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

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %):
Not determined.

FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

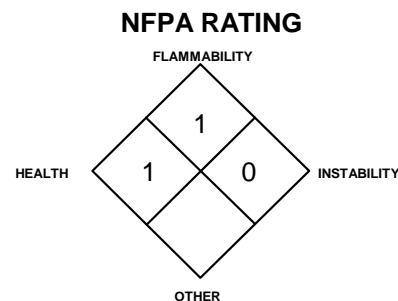
UNSUITABLE EXTINGUISHING MEDIA: None known.

SPECIFIC HAZARDS ARISING FROM THE PRODUCT: This product may ignite if highly heated for a prolonged period of time. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., aluminum, carbon, sulfur and magnesium oxides).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

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. Contaminated protective equipment 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.



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

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people.

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g., 1 vial of tablets), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., a pallet of vials), protective apparel should be used with a respirator when there is any danger of airborne dusts being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit.

METHODS FOR CLEANUP AND CONTAINMENT:

Small Spills: Pick-up or sweep-up spilled tablets.

Large Spills: Trained personnel following pre-planned procedures should handle non-incident releases. Access to the spill areas should be restricted. Sweep up spilled product carefully, avoiding the generation of airborne dusts.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Move to a secure area. 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

PRECAUTIONS FOR SAFE HANDLING: Employees must be trained to properly use this compound. Particular care in working with this material must be practiced in pharmacies and other preparation areas, during manufacture of pharmaceutical preparations, and during patient administration. Use of this compound should be performed in a designated area for working with narcotic compounds. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics in work areas where this product is handled or stored. Wash thoroughly after handling this product or equipment and containers of this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Use of this product should be performed in a designated area for working with drugs. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. If necessary, work areas must be regularly cleaned and decontaminated.

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

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store this product in original container. Store at 20°C to 25°C (68°F to 77°F). (See USP Controlled Room Temperature.) Inspect bottles containing this product for leaks or damage. Store away from incompatible materials (see Section 10, Stability and Reactivity).

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

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	
Sucralfate	54182-58-0	NE	NE	NE	NE	NE	NE	NE	Actavis WEL: 1000 µg/m ³
Corn Starch	9005-25-8	10	NE	15 (total dust); 5 (resp. fraction)	NE	10 (total dust); 5 (resp. fract.)	NE	NE	Carcinogen: TLV-A4
D&C Red No. 30 Aluminum Lake	1342-90-1	NE	NE	NE	NE	NE	NE	NEN	NE
FD&C Red No. 1 Lake	25956-17-6	NE	NE	NE	NE	NE	NE	NE	NE
Microcrystalline Cellulose Exposure limits are for cellulose	9004-34-6	10	NE	15 (total dust), 5 (resp. fract.)	NE	10 (total dust), 5 (resp. fract.)	NE	NE	NE
Magnesium Stearate Exposure limits are for Stearates	557-04-0	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4

NE = Not Established.

International Occupational Exposure Limits: In addition to the exposure limit values cited in this section, other exposure limits have been established by various countries for the 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)/m³, JAN 2002
Russia: STEL = 2 mg/m³, JUN 2003

CORN STARCH:

Belgium: TWA = 10 mg/m³, MAR 2002
Korea: TWA = 10 mg/m³, 2006

CORN STARCH (continued):

New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
Russia: STEL = 10 mg/m³, JUN 2003
Switzerland: MAK-W = 3 mg/m³, DEC 2006
United Kingdom: TWA = 10 mg/m³ (inhalable dust), OCT 2007
United Kingdom: TWA = 4 mg/m³ (respirable dust), OCT 2007

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

International Occupational Exposure Limits (continued):

MAGNESIUM STEARATE:

New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002

MICROCRYSTALLINE CELLULOSE:

Belgium: TWA = 10 mg/m³, MAR 2002

France: VME = 10 mg/m³, FEB 2006

Korea: TWA = 10 mg/m³, 2006

Mexico: TWA = 10 mg/m³; STEL = 20 mg/m³, 2004

The Netherlands: MAC-TGG = 2 mg/m³, 2003

MICROCRYSTALLINE CELLULOSE (continued):

New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002

Russia: STEL = 10 mg/m³, JUN 2003

Switzerland: MAK-W = W 6 mg/m³, DEC 2006

United Kingdom: TWA = 10 mg/m³ (inhalable), 2005

United Kingdom: TWA = 4 mg/m³; STEL = 20 mg/m³ (respirable), 2005

In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam, check ACGIH TLV

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: 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.

Eye Protection: No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, splash goggles or safety glasses should be considered.

Hand Protection: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. 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: Oblong tablets.

ODOR: Odorless.

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.

MOLECULAR WEIGHT: 1448.68

ODOR: Odorless.

MELTING POINT: Not available.

VAPOR PRESSURE (air = 1) @ 25°C: 0 Not available.

EVAPORATION RATE (nBuAc = 1): Not applicable.

SOLUBILITY IN WATER: Practically insoluble.

OTHER SOLUBILITIES: Soluble in dilute hydrochloric acid and sodium hydroxide solution. Practically insoluble in ethanol, chloroform.

COEFFICIENT WATER/OIL DISTRIBUTION: Not available.

COLOR: As described in Section 2.

ODOR THRESHOLD: Not applicable.

COLOR: White.

MOLECULAR FORMULA: C₁₁H₂₈Al₈O₅S₈

ODOR THRESHOLD: Odorless.

pH: Not available.

SPECIFIC GRAVITY (water = 1): Not available.

FLASH POINT: Not available.

BOILING POINT @ 760 mmHg: Not available.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is not reactive.

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, sulfur and magnesium oxides). *Hydrolysis:* None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids and alkalies, and other chemicals that could affect its performance should be avoided.

POSSIBILITY HAZARDOUS REACTION/POLYMERIZATION: Will not occur.

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 medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Inhalation of dusts generated by damaged tablets of this product may slightly irritate the nose, throat, and lungs. No other health effects from inhalation known.

Contact with Skin or Eyes: It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness. Symptoms of eye contact can include redness, pain, and watering (mechanical irritation).

Skin Absorption: No information is available on possible skin absorption.

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: Injection is not a likely route of exposure for the form of this product.

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.

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses (continued): 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: Accidental ingestion may be harmful.

Chronic: Chronic therapeutic use or workplace exposure may cause effects described under 'Other Potential 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: Dusts from this product may irritate contaminated tissue.

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: The following toxicity data are currently available for the active ingredient. Data are available for excipients, but are not provided 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
 LD₅₀ (Oral-Rat) > 12 gm/kg
 LD₅₀ (Oral-Mouse) > 8 gm/kg

SULCRAFATE (continued):

LD₅₀ (Intraperitoneal-Rat) >4 gm/kg
 LD₅₀ (Intraperitoneal-Mouse) >8 gm/kg
 LD₅₀ (Subcutaneous-Rat) >4 gm/kg
 LD₅₀ (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:

PREGELATINIZED CORN STARCH, MAGNESIUM STEARATE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)

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.



HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

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

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential.

ECOTOXICITY: This product may be harmful to aquatic and terrestrial organisms; all releases to terrestrial, atmospheric and aquatic environments should be avoided. No aquatic toxicity data are available for the active ingredient.

OTHER ADVERSE EFFECTS: This product does not contain any component with known ozone depletion potential.

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.

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.

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

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

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

14. TRANSPORTATION INFORMATION

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

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: 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) DESIGNATION: This product is not classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): 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 does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and no component is specifically 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 is exempted from requirements of the DSL/NDL 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.

15. REGULATORY INFORMATION (Continued)

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

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. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. Do not take internally without prescription. Avoid contact with skin, eyes, and clothing. Keep container closed. Use gloves, safety glasses, and appropriate respiratory and body protection. **FIRST-AID:** If exposed, seek immediate medical attention. If swallowed, do not induce vomiting. If alert, give victim up to three glasses of water. Never give anything by mouth to an unconscious person. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. Remove contaminated clothing and shoes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. **IN CASE OF FIRE:** Use water fog, dry chemical or CO₂, or alcohol foam. **IN CASE OF SPILL:** Refer to Safety Data Sheet for complete spill response procedures. Spill response should be performed by persons properly trained to do so. Decontaminate area with bleach and detergent solution and triple rinse area. Place spill debris in a suitable container. Refer to SDS 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.

EU LABELING AND CLASSIFICATION 67/548/EEC: 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 FOR COMPONENTS:

Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:

All Components: No classification has been published or is applicable.

Full Text EU 67/548/EEC:

All Components: No classification has been published or 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.

This Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Actavis, Inc. knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

DATE OF PRINTING: September 2, 2014



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

Product Identifier

Material Name: Sucralfate Tablets (Greenstone LLC)

Trade Name: Not established
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antacid

Details of the Supplier of the Safety Data Sheet

Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Sucralfate	54182-58-0	259-018-4	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:	No data available
Medical Conditions Aggravated by Exposure:	None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:	None
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5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting 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 Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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7. HANDLING AND STORAGE

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³

Corn Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

Exposure Controls

Engineering Controls:

General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

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Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Microcrystalline cellulose

No data available

Sucralfate

No data available

Corn Starch

No data available

Magnesium Stearate

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

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

Hazardous Decomposition Products: No data available

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11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Known Clinical Effects: Adverse effects associated with therapeutic use include constipation, abdominal pain, diarrhea, nausea, headache.

Acute Toxicity: (Species, Route, End Point, Dose)

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Sucralfate

Rat Oral LD50 > 12 g/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sucralfate

6 Month(s) Rat No route specified 4000 mg/kg/day NOAEL No effects at maximum dose
1 Month(s) Rat No route specified 8000 mg/kg/ 2xday No effects at maximum dose

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Sucralfate

Reproductive & Fertility Rat Oral 3000 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Mouse Oral 4000 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rat Oral 1000 mg/kg/day NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Sucralfate

Dominant Lethal Assay Mouse Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Sucralfate

24 Month(s) Mouse Oral 1 g/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

Microcrystalline cellulose

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

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15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9
Corn Starch	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6
Sucralfate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	259-018-4
Magnesium Stearate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Data Sources:	Safety data sheets for individual ingredients. Publicly available toxicity information.
Reasons for Revision:	New data sheet.
Revision date:	15-Dec-2016
Prepared by:	Product Stewardship Hazard Communication Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time

End of Safety Data Sheet