SAFETY DATA SHEETS

This SDS packet was issued with item:

078863483

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078863491 078939959 078942891

NOSTRUM
LABORATORIES, INC.

SAFETY DATA SHEET

Sucralfate Tablets USP, 1 Gram

Section 1. Identification of the Substance and the Company Undertaking

1.1 Product Name: Sucralfate Tablets USP

Synonyms: Sucrose octasulfate-aluminum complex, Beta-D-fructofuransyl-alpha-D-glucopyranoside octakis aluminum.

Chemical Name: a-D-glucopyranoside, B-D-fructofuranosyl-octakis-(hydrogen sulfate), aluminum complex.

Classification: Sucrose Octasulfate aluminum salt/ anti-ulcer drug

CAS No: 54182-58-0

EC No.: 259-018-4

Manufacturer/Supplier: Nostrum Laboratories Inc.
1800 N. Topping Avenue
Kansas City, MO 64120
quality@nostrumlabs.com

Emergency Telephone Number: +1-888-886-2027

1.2 Relevant Identified Uses of the Substance and Uses Advised Against:

Relevant Uses:

Anti-ulcer agent for the treatment of and maintenance therapy of peptic and duodenal ulcer disease.

Recommended Dosage(s):

Adults with Active Ulcer Disease: 1 g by mouth 4 times a day for 4 – 8 weeks

Adults Maintenance Therapy: 1 g 2 by mouth times a day

Uses Advised Against:

Contraindicated for patients who have hypersensitivity reactions to sucralfate or any of its excipients.

Section 2. Hazards Identification

Emergency Overview:

This medication contains an active pharmaceutical ingredient that can harm bodily functions; handle with caution. Not expected to be a hazard in tablet form.

Target Organs: Gastrointestinal tract

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.

OSHA Hazards: Not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122).

GHS Classification: No GHS label required

Acute toxicity: Not required

GHS Label Elements, Including Precautionary Statements:

Pictogram: Not required.

Signal word: Not required

Hazard statements: None

Precautionary Statements:

P264: Wash hands thoroughly after handling product

HMIS Classification:

Health hazard: 1

Flammability: 1

Physical hazards: No data available

NFPA Rating:

Health hazard: No data available

Fire: 1

Reactivity hazard: No data available

Potential Health Effects:

Inhalation: In the workplace dusts from product may cause respiratory irritation.

Skin: In the workplace product may cause skin irritation.

Eyes: In the workplace dusts may cause eye irritation.

Ingestion: In the event of an overdose, there is a very minimal risk of the development of dyspepsia, abdominal pain, nausea, and vomiting.

Section 3. Composition/Information on Ingredients

Molecular Formula: $Al_8(OH)_{16}(C_{12}H_{14}O_{35}S_8)[AlCOH_3]x[H_2O]y$

$X = 8 - 10 \quad Y = 22 - 31$ (API)

Molecular Weight: 252.27 g/mole (API)

Excipients: Povidone USP, colloidal silicon dioxide NF, magnesium stearate NF, and purified water

Section 4. First Aid Measures

General:

If Inhaled: Move person to fresh air and keep patient at rest. If not breathing, give artificial respiration or oxygen by trained personnel; obtain immediate medical attention.

If Skin Contact: Immediately wash affected area with plenty of soap and water for at least 15 minutes and remove contaminated clothing. If irritation persists get medical attention.

If Eye Contact: Remove contact lenses if present, hold eyelids apart and flush with water for at

at least 15 minutes. If symptoms persist get immediate medical attention.

If Ingested: If patient is conscious rinse out mouth with water; never give anything by mouth to an unconscious patient. Do not induce vomiting unless directed to do so by medical personnel.

The Most Important Symptoms and Effects:

Symptoms: Puritis, dizziness, insomnia, nausea, gastric discomfort, indegestion, vertigo, sleepyness, back pain, and headache.

Effects: Dry mouth, flatulence, dyspnea, lip swelling, rash, and other effects from hypersensitivity (rare), anaphylaxis, bronchospasm, pharyngeal and laryngeal edema & urticaria.

Section 5. Firefighting Measures:

Extinguishing media: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.

Protective equipment and precautions for firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, (NIOSH approved or equivalent), and full protective gear to prevent direct contact with lungs, skin, and eyes.

Specific hazards arising from the chemical: Products of decomposition may release CO, CO_2, SO_2, SO_3, and some metalic oxides.

Firefighting Measures: Firefighters whose protective equipment becomes contaminated should Thoroughly shower with warm, soapy water and should receive medical evalution if they experience any adverse effects.

Specific methods: Incipient fire responders should wear eye protection and structural firefighters should wear self-contained breathing apparatus equipment, and full protective gear. Evaquate unecessary personnel away from the scence to safety.

Section 6. Accidental Release Measures:

Release to land: In the event of a spill clear the area and protect people from exposure.

Small Spills: (i.e. 1 bottle of tablets), wear double nitrile gloves and eyewear protection.

Large Spills: (i.e. a pallet of bottles of tablets), rubber gloves, rubber boots, face shield, & Tyvek suits should be utilized. If clean-up risks the generation of significant amounts of dust, a respirator device should be used.

Release to air: Ensure adequate ventilation; use personal protective equipment, (not considered to be a risk/complication when drug is in finished tablet form).

Release to water: Prevent material from entering sewer or confined spaces, waterways, or public waters; do not flush to the sewer. For spills, contain, minimize dispersion and collect.

Handling Significant Quantities of Broken Capsules: Sweep up or vacuum up spilage, avoid dust formation, collect in a suitable container for disposal and avoid allowing chemicals drug particles from entering the environment including drains, toilets, sinks, etc.

Personal precautions: Wear protective clothing, gloves, etc. as appropriate, evacuate all non-essential personnel from the area.

Section 7. Handling and Storage

Precautions: Ensure adequate ventilation; wear personal protective equipment/clothing; avoid contact with skin, eyes, and clothing, avoid dust formation. Not expected to be a risk when working with the tablet form.

Storage: Store in a dry, cool, and well ventilated place; keep container tightly closed; and keep out of the reach of children. Store as directed by product packaging instructions.

Section 8. Exposure Controls/Personal Protection:

Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne dust/particle levels below the exposure limit. Not expected to be a risk in tablet form.

Personal Protection: Not required when handling sealed tablets or containers, if necessary wear safety glasses, a lab coat, and gloves.

Exposure Controls/Personal Protection: Not established.

Biological limits: No data available

Exposure guidelines: Do not allow product to enter drains.

Section 9. Physical and Chemical Properties:

Appearance: White, oblong, bisected tablets debossed by "N" and "S1" on one side.

100 count: NDC # 29033-003-01

500 count: NLC # 29033-003-05

Odor: Near odorless

pH: 4.0 – 5.0 in 10 mL of water (API)

Melting Point: > 200°C

Freezing Point: Not available

Initial Boiling Point: Not available

Flash Point: Not available

Evaporation Rate: Not available

Flammability: Slightly flammable to flammable in the presence of heat

Upper/Lower Flammability or Explosive Limits: Not available

Vapor Density: Not available

Vapor Pressure: Not available

Relative Density: Not available

Physical and Chemical Properties:

Solubility: Insoluble in water, ethanol, & chloroform; soluble in dilute HCl and sodium hydroxide

Partition Coefficient: n-octanol/water: Not available

Viscocity: Not available

Auto-Ignition Temperature: Not available

Dispersion Properties: Not available

Section 10. Stability and Reactivity

Reactivity: Stable under normal conditions

Chemical Stability: Stable under normal condidtions

Possibility of Hazardous Reactions:

Conditions to Avoid: Close proximity to strong oxidizing agents, exposure to heat & light.

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: Oxides of carbon and sulfur

Polymerization: Will not occur

Section 11. Toxicological Information

Routes of Exposure: Inhalation, eye & skin contact and oral exposure.

Acute Toxicity: Oral LD50 – Rat: > 12 g/kg

Mouse: > 8 g/kg

Human: > 20 mg/kg/10M

Toxicological Information:

Skin: Direct contact may cause irritation, itching, and reddness.

Eye: Direct contact may cause redness, pain, and watering.

Ingestion: Sucralfate is only minimally absorbed from the gastrointestinal tract; in animal studies doses up to 12 g/kg failed to produce lethal effects.

Symptoms related to the physical, chemical and toxicological characteristics:

Refer to section 4.0

Specific target organ toxicity – repeated exposure: Chronic use may cause diarrhea, nausea, vomiting, indigestion, flatulence, bezoar formation, dyspepsia, and dry mouth.

Genetic Toxicity in Humans: There are no adequate current studies of the use of sucralfate in pregnant women, however the drug is not expected to cause harm to the fetus if administered to a pregnant woman. Sucralfate is rated by the FDA as Pregnancy Risk Category B. Sucralfate has tested negative for genotoxic potential

Delayed and immediate effects of exposure: There are no current Biological Exposure Indices, (BEIs) determined for sucralfate.

Medical conditions aggravated by exposure:

Hypersensitivity reactions to sucralfate and/or excipients

May agravate medical conditions in patients who are immunocompromised.

Section 12. Ecological Information

Ecotoxicity: Large releases may be harmful to aquatic and terrestrial organisms; take precautions against releasing sucrafate into the environment, do not allow product to enter drains or waterways.

Persistance and degradability: This product has not been tested for persistance and degradeability.

Bioaccumulation potential: This product has not been tested for biaccumulation potential.

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

Section 13. Disposal Considerations

Disposal Instructions: The generation of waste should be avoided or minimized whenever possible. Disposal of this product should comply with the requirements of environmental protection & waste disposal legislation & any federal, regional, local authority requirements. Dispose of surplus and non-recyclable products via a licensed medical waste disposal contractor.

Contaminated packaging: Empty containers or packaging may retain product residues, avoid dispersal of spilled material and/or runoff to come in direct contact with soil, waterways, drains, & sewers.

Section 14. Transport Information

DOT: Not classified as dangerous goods under 49 CFR 172.101.

ICAO: Not classified as dangerous goods.

IATA: Not classified as dangerous goods.

IMO: Not classified as dangerous goods.

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC code):

not applicable.

Section 15. Regulatory Information

U.S. Federal Regulations:

TSCA 12(b): Not listed

SARA:

SARA 302 Extremely hazardous substance: Not required

SARA 304 Emergency release notification: Not regulated

SARA 311/312 Hazardous chemical: Not required

SARA 313 (TRI reporting): Not regulat

Other Federal Regulations:

U.S. CERCLA Reportable Quantities: Not applicable

Safe Drinking Water Act: Not available

Clean Air Act: This substance does not contain any hazardous air pollutants as definded by the U.S. Clean Air Act Section 112 (40 CFR 61, 68, 130).

FDA: Regulations of the FDA are applicable when this material is used in pharmaceutical preparations and are subject to FDA labeling requirements but are exempt from the Hazard Communication Standard (HCS) labeling requirements. However a safety data sheet is required for the drug.

U.S. State Regulations:

California Prop. 65: This product does not contain any chemicals known to cause cancer, birth defects, or any other reproductive harm.

U.S. State Right-to-Know Regulations: Not applicable

International Inventories:

AICS (Australia): Data not available

DSL (Canada): No

NDSL (Canada): No

IECSC (China): Data not available

EINECS (Europe): Yes

ELINCS (Europe): Yes

ENCS (Japan): Data not available

ECL (Korea): Data not available

New Zealand Inventory: Data not available

PICCS (Philippines): Data not available

INSQ (Mexico): Data not available

Turkish Chemical Inventory: Data not available

****A yes indicates that all components of this product comply with the inventory requirements* administered *by the governing country(s)****.

Section 16. Other Information

Issue date: FEB 19 2020

Revision #: 00

References:

1. NLI "Sucralfate Tablets USP, 1 g Prescribing Instructions", 01-29-2020.
2. EUTICALS S.p.A., "Common Technical Document by Applicant, Sucralfate", October, 2019.
3. Actavis, "Sucralfate Tablet Safety Data Sheet", August 30, 2014.
4. Allergan, "Sucralfate Suspension Safety Data Sheet", 02-Oct-2018.

SEE THE CURRENT PACKAGE INSERT FOR FURTHER DETAILS

Disclaimer:

The information provided herein is believed to be accurate and complete. If this product deteriorates, becomes contaminated, or is combined with other materials, potential hazards may be present that are not mentioned in this SDS. It is the consumers responsibility to use the information herein according to the application. Nosturm Laboratories, Inc. assumes no responsibility or liability resulting from the use or misuse of this information.