NOSTRUM
LABORATORIES, INC.

MATERIAL SAFETY DATA SHEET

MANUFACTURER INFORMATION
Nostrum Laboratories, Inc. 1800 North Topping Avenue Kansas City, MO 64120

1. CHEMICAL PRODUCT IDENTIFICATION	
Common/Trade Name	Sucralfate Tablets, USP
Chemical Name **(Predominant & Active Ingredient)**	α-D-glucopyranoside, β-D-fructofuranosyl-octakis-(hydrogen sulfate), aluminum complex
Synonyms **(Predominant & Active Ingredient)**	Ulcerlmin, Carafate, Sucrose Octasulfate-Aluminum Complex, Beta-D-Fructofuransyl-alpha-D-glucopyranoside octakis aluminum
Molecular Formula **(Predominant & Active Ingredient)**	$C_{12}H_{54}Al_{16}O_{75}S_8$
Molecular Weight **(Predominant & Active Ingredient)**	2086.74
CAS Number **(Predominant & Active Ingredient)**	54182-58-0
Chemical Family **(Predominant & Active Ingredient)**	Sucrose Octasulfate aluminum salt
Product Indications/Usage	Short-term treatment of active duodenal ulcers and maintenance therapy for duodenal ulcer patients

2. COMPOSITION / ACTIVE INGREDIENT INFORMATION		
Composition	**CAS Number**	**Exposure Limit**
Sucralfate	54182-58-0	None Established

3. HAZARD IDENTIFICATION	
Emergency Overview	**Physical Description:** White, scored, oblong tablets embossed with "N" and "S1" containing not less than 90.0% and not more than 110.0% of the labeled amount of 1 gram Sucralfate, USP
	Color: White
	Odor: No Data Available
	WARNINGS: • **Eye irritation on contact** • **Skin irritation on contact**

MATERIAL SAFETY DATA SHEET

3. HAZARD IDENTIFICATION Continued	
Primary Route(s) of Entry	Oral administration
Potential Health Effects	**Ingestion:** With overdose, very minimal risk but in rare cases may cause dyspepsia, abdominal pain, nausea, and vomiting
	Inhalation: Not expected to be an inhalation hazard in the final pharmaceutical form
	Eye Exposure: Not expected to be an eye hazard in the final pharmaceutical form
	Skin Exposure: Not expected to be a skin hazard; if occurs, may cause hypersensitive reactions resulting in rash, redness, itching, and inflammation
Toxicity Data	See Section 11 – Toxicological Information
Effects of Overexposure	The potential for exposure is reduced in the finished pharmaceutical form. The signs of overdosage are usually very rare and limited to dyspepsia, abdominal pain, nausea, and vomiting which are generally reversible with supportive care.
Target Organs	Gastrointestinal tract

4. FIRST AID MEASURES	
Ingestion	Do not induce vomiting, unless directed by medical personnel. Never administer anything orally, if the victim is unconscious. Loosen tight clothing such as a collar, tie, belt, or waistband. Seek immediate medical attention.
Inhalation	Allow the victim to rest in a well-ventilated area. Perform CPR, if the victim is not breathing. Administer oxygen, if breathing is difficult. Seek immediate medical attention.
Eye Exposure	Check for and remove contact lenses. Flush the eyes with running water for at least 15 minutes with the eyelids open. Seek immediate medical attention.
Skin Exposure	Wash the contaminated area thoroughly with plenty of water and non-abrasive soap. Apply an emollient to irritated skin. If irritation persists, seek immediate medical attention.

MATERIAL SAFETY DATA SHEET

5. FIRE AND EXPLOSION HAZARDS	
Flammability	May be combustible at high temperatures
Flash Point	Not Available
Auto-Ignition	Not Available
Flammable Limits	Not Available
Fire Hazard in the Presence of Various Substances	Slightly flammable to flammable in the presence of heat
Extinguishing Media	Dry Chemicals: carbon oxides (CO, CO_2), sulfur oxides (SO_2, SO_3), and some metallic oxides
Special Fire Fighting Procedure	Wear a self-contained breathing apparatus and protective clothing to prevent contact with lungs, eyes, and skin.
Unusual Fire/Explosion Hazards	N/A
Hazardous Combustion Products	Use a dry, chemical powder or an appropriate foam.

6. ACCIDENTAL RELEASE INFORMATION	
Environmental Protection Measures	Do not release into water/sewer lines.
Cleaning/Absorption Procedure	Sweep up and place in a bag. Avoid raising dust. Hold for waste disposal. Ventilate the area and wash the spill site with plenty of water.

7. PRECAUTIONS FOR SAFE HANDLING AND STORAGE	
Precautions	Keep in a cool, well-ventilated area away from incompatible substances, such as oxidizing agents. Keep away from heat or other sources of ignition.
Storage	Store in a tight, light-resistant container at the proper temperature: 20°-25°C (68°-77°F)

8. CONTROL MEASURES & PERSONAL PROTECTIVE EQUIPMENT	
Exposure Limits	Not Available
Engineering Controls	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below the recommended exposure limit.
Respiratory Protection	Not Required when handling sealed or open tablet containers
Personal Protection	Not Required when handling sealed or open tablet containers

MATERIAL SAFETY DATA SHEET

9. PHYSICAL / CHEMICAL CHARACTERISTICS	
Appearance	White, solid, scored, oblong tablets embossed with "N" and "S1" containing 1 gram Sucralfate, USP
Odor	Odorless
Taste	Not Available
Color	White
Molecular Weight	2086.74 g/mole
pH	N/A
Melting Point	Not Available
Boiling Point	Not Available
Vapor Pressure	N/A
Volatility	Not Available
Solubility in Water	Not Available
Specific Gravity	Not Available
Vapor Density	Not Available
Flammability Limits	Not Available

10. STABILITY & REACTIVITY DATA	
Stability	Stable
Incompatibility with Various Substances	Reactive with oxidizing agents
Corrosivity	Non-Corrosive
Hazardous Decomposition	Oxides of carbon and oxides of sulfur
Conditions to Avoid	Excessive Heat
Hazardous Polymerization	No Occurence

NOSTRUM
LABORATORIES, INC.

MATERIAL SAFETY DATA SHEET

11. TOXICOLOGICAL INFORMATION	
Acute Oral Toxicity LD_{50}	Mouse - > 8000 mg/Kg
LD_{50} (Inhalation)	Not Available
Carcinogenesis **Mutagenesis** **Impairment of Fertility**	Chronic toxicity studies have been carried out in mice and rats at doses up to 1 g/kg (12 times the human dose). There was no evidence of drug-related tumorgenicity. Mutagenicity studies were not conducted. Reproductive studies in rats at doses up to 38 times the human dose revealed no indication of fertility impairment.

12. ENVIRONMENTAL IMPACT INFORMATION
No data is currently available on the environmental impact of this product.

13. DISPOSAL INFORMATION	
Waste Disposal Considerations	Dispose of material according to federal, state, and local disposal regulations.
Home Disposal	Discard away from the reach of children.

14. TRANSPORTATION INFORMATION	
DOT **TDG** **IATA** **IMDG**	**This product is not subject to regulations for the safe transport of hazardous chemicals.**

15. REGULATORY INFORMATION	
NDC Number	29033-003-01 29033-003-05
FDA	Sucralfate is a prescription medication approved for short-term treatment of active duodenal ulcers and maintenance therapy for duodenal ulcer patients.
DEA	Sucralfate is not a controlled substance.
WHMIS Classification	Not controlled by Workplace Hazardous Materials Information System (WHMIS)

16. MISCELLANEOUS INFORMATION	
Abbreviations	**N/A** – Not Applicable
References	• Sucralfate Tablets, USP Package Insert Nostrum Laboratories, Inc., Kansas City, MO • RTECS (Registry of Toxic Effects of Chemical Substances) Number: APRD01238 • Regulatory and ChemExpert Database
SEE THE CURRENT PACKAGE INSERT FOR FURTHER DETAILS	

NOSTRUM
LABORATORIES, INC.

MATERIAL SAFETY DATA SHEET

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 MSDS. It is the consumer's responsibility to use the information herein according to the application. Nostrum Laboratories, Inc. assumes no responsibility or liability resulting from the use or misuse of this information.