
EMERGENCY OVERVIEW

Each Sucralfate Tablet USP intended for oral administration contains Sucralfate and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

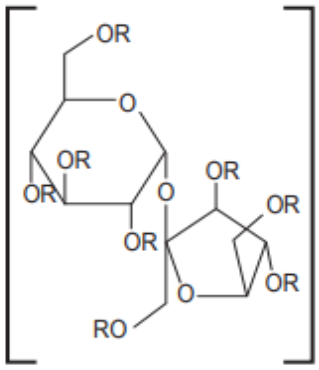
Section 1. Identification

Identification of the product

Product Name: Sucralfate Tablet USP

Formula: α-D-glucopyranoside, β-D fructofuranosyl-, octakis- (hydrogen sulfate), aluminum complex.

Chemical Name:



$[Al(OH)_3]$ x $[H_2O]y$

(x=8 to 10 and y= 22 to 31)

R= $SO_3Al(OH)_2$

Manufacturer / supplier identification

Company:	**Zydus Lifesciences Limited, Matoda, India**
Address:	Zydus Lifesciences Limited, Plot No- 1A/1 & 2, Pharmez Special Economic Zone, Sarkhej- Bavla N.H. No. 8A, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad-382 213, India
Contact for information:	Tel: +91-79-26868100 Fax: +91-79-26868533
Emergency Telephone No.	Tel: +91-79-26868101
US Customer Service No.	1 (877) 993 8779
Recommended use / Therapeutic Category	Antiulcer

Restriction on Use / Contraindications:	Sucralfate tablets are contraindicated in patients with known hypersensitivity reactions to the active substance or to any of the excipients.

Section 2. Hazard(s) Identification

Dose and Administration	Active Duodenal Ulcer. The recommended adult oral dosage for duodenal ulcer is 1 g four times per day on an empty stomach. Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate. While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.
Adverse Effects	Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,700 patients treated with sucralfate tablets, adverse effects were reported in 129 (4.7%). Constipation was the most frequent complaint (2%). Other adverse effects reported in less than 0.5% of the patients are listed below by body system: **Gastrointestinal:** diarrhea, nausea, vomiting, gastric discomfort, indigestion, flatulence, dry mouth **Dermatological:** pruritus, rash **Nervous System:** dizziness, insomnia, sleepiness, vertigo **Other:** back pain, headache
Over Dose Effect	Due to limited experience in humans with overdosage of sucralfate, no specific treatment recommendations can be given. 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. Risks associated with acute overdosage should, therefore, be minimal. In rare reports describing sucralfate overdose, most patients remained asymptomatic. Those few reports where adverse events were

described included symptoms of dyspepsia, abdominal pain, nausea, and vomiting.

Pregnancy Comments

Teratogenicity studies have been performed in animal at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Pregnancy Category

Category B

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Sucralfate USP	4.4 mg/day	54182-58-0
Inactive ingredients:		
Corn Starch	Not Found	9005-25-8
Microcrystalline Cellulose	Not Found	9004-34-6
Magnesium Stearate	Not Found	557-04-0

Section 4. First -aid measures

General

- **Eyes Contact:** Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel
- **Skin Contact:** Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
- **Inhalation**: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
- **Ingestion:** Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. Fire -fighting measures	
Suitable Extinguishing Media	Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers
Unsuitable Extinguishing Media	A solid water stream may be inefficient.
Fire Fighting Instructions:	As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes
Section 6. Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
Environmental precautions:	Take steps to avoid release into the environment, if safe to do so.
Methods and material for containment and cleaning up:	Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.
Section 7. Handling and Storage	
Precautions To Be Taken in Handling:	Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure
Precautions To Be Taken in Storing:	Keep container tightly closed. Store in accordance with information listed on the product insert
Section 8. Exposure controls / personal protection	
Engineering Controls:	Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.
Personal protection equipment:	**Eye Protection:** Safety glasses **Protective Gloves:** Compatible chemical-resistant gloves **Other Protective Clothing:** Lab coat **Respiratory Equipment** NIOSH approved respirator, as conditions warrant.

Section 9. Physical and chemical properties			
Physical States/ Appearance	White to off-white, capsule shaped, biconvex, scored, uncoated tablet debossed with "6" and "75" on either side of score and plain on the other side.		
Solubility	Not determined.	**Odour**	Characteristic
Boiling point	Undetermined	**Melting Point**	Undetermined
Evaporation rate	Not available.	**Density**	Not determined.
Reactivity in water	Not available.	**Vapour Density**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.

Section 10. Stability and Reactivity	
Reactivity	No further relevant information available.
Thermal decomposition / conditions to be avoided:	No decomposition if used according to specifications.
Possibility of hazardous reactions	No dangerous reaction known
Conditions to avoid	No further relevant information available.
Incompatible materials	Strong Oxidizing agent
Hazardous decomposition products:	Aluminum oxides, carbon dioxide, carbon monoxide, sulfur oxides

Section 11. Toxicological information	
Information on Toxicological Effects:	The toxicological effects of this product have not been thoroughly studied. Sucralfate - Toxicity Data: Oral TDLO (infant): 1276 mg/kg/3D (intermittent); Oral LD50 (rat): >12 gm/kg; Intraperitoneal LD50 (rat): >4 gm/kg; Subcutaneous LD50 (rat): >4 gm/kg; Oral LD50 (mouse): >8 gm/kg; Intraperitoneal LD50 (mouse): >8 gm/kg; Subcutaneous LD50 (mouse): >8 gm/kg; Oral TDLO (human): 20 mg/kg/10M.
Chronic Toxicological Effects:	Sucralfate - Investigated as a drug. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. Sucralfate RTECS Number: BD0900000

Section 12. Ecological information

Toxicity

Aquatic toxicity: No further relevant information available. ·

Persistence and degradability No further relevant information available.

Bioaccumulative potential No further relevant information available.

Mobility in soil No further relevant information available. ·

Additional ecological information:

General notes: Water hazard class 1 (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Section 13. Disposal Consideration

Waste treatment methods

Smaller quantities can be disposed of with household waste.

Recommendation

Uncleaned packaging

Disposal must be made according to official regulations.

Recommendation:

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / AND.

Section 15. Regulatory Information

Under Approval

Section 16. Other information

None

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The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.