



**IN CASE OF EMERGENCY CALL:**  
National Poison Control 800-222-1222

## Material Safety Data Sheet

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: **Sucralfate Suspension**  
CAS No: 54182-58  
Chemical Name:  $\alpha$ -D-glucopyranoside,  $\beta$ -D-fructofuranosyl-, octakis-(hydrogen sulfate), aluminum complex  
Chemical Formula:  $C_{12}O_{11}H_{12}-8(SO_3[Al_2(OH)_5 \cdot (H_2O)_2])$   
Molecular Weight:  
Product Use: Short-term (up to 8 weeks) treatment of active duodenal ulcer.  
  
Manufacturer's Name: VistaPharm, Inc.  
Address: 7265 Ulmerton Road  
Largo, FL 33771

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Sucralfate (1g/10mL) active ingredient

Please refer to current package insert for other components.

### 3. HAZARDS IDENTIFICATION

Emergency Overview      Physical State: Pink suspension  
  
Odor: Cherry

Primary Route of Entry:      Ingestion

CARAFATE Suspension is indicated in the short-term (up to 8 weeks) treatment of active duodenal ulcer. May occasionally produce constipation.

The recommended adult oral dosage for duodenal ulcer is 1 gm (10mL/2teaspoonfuls) four times per day.

Acute oral studies in animals, however, using doses up to 12 gm/kg body weight, could not find a lethal dose. Risks associated with overdosage should, therefore, be minimal.

### 4. FIRST AID MEASURES

Eye Exposure:      Any material that contacts the eye should be washed out immediately with water. Obtain medical attention if symptoms persist.

Skin Exposure:      Wash affected area with soap and water. Remove contaminated clothing and shoes immediately. Obtain medical attention if symptoms occur.

Inhalation: Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Obtain medical attention immediately.

Ingestion: Call a physician or poison control center immediately.

#### **5. FIRE AND EXPLOSION HAZARD**

Flash Point: Not determined.

Extinguishing Media: Use water spray, dry chemical, carbon dioxide, foam or material appropriate for fire in surrounding area.

Fire Fighting Procedures: Wear full protective clothing and self-contained breathing apparatus.

Hazardous Combustion Products: Not determined.

#### **6. ACCIDENTAL RELEASE MEASURES**

If Material is Spilled or Released: Impervious gloves of rubber or other material should be worn when handling spills of this product. Spills should be mopped or wiped up and disposed of in accordance with appropriate applicable federal, state, and local laws.

#### **7. HANDLING AND STORAGE**

Handling: Observe good industrial hygiene practices. Shake well before using.

Storage: Store at controlled room temperature 20° and 25°C (68° to 77°F). Avoid freezing.

#### **8. EXPOSURE CONTROLS AND PERSONAL PROTECTION**

OSHA Exposure Limits: None

#### **9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance and Odor: Pink suspension and cherry odor

#### **10. STABILITY AND REACTIVITY**

Chemical Stability: Stable under normal conditions.

Conditions to avoid: Excessive heat or cold.

Hazardous Decomposition: None

Hazardous Polymerization: Will not occur.

#### **11. TOXICOLOGICAL INFORMATION**

Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats up to 1 gm/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment.

Mutagenicity studies were not conducted.

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. 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.

**12. ECOLOGICAL INFORMATION**

Environmental Effects : Not determined.

**13. WASTE DISPOSAL INFORMATION**

Waste Disposal Considerations: Dispose of this material in accordance with applicable international, national, state and local waste disposal regulations.

At Home: Discard away from children's reach.

**14. TRANSPORTATION INFORMATION**

This material is not regulated as hazardous by US-DOT.

**15. REGULATORY INFORMATION**

FDA: Sucralfate is an approved prescription medication.

**16. DISCLAIMER**

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. VistaPharm, Inc. assumes no responsibility for the use of this information.

Date: June 2009

**SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION**