



## Safety Data Sheet

### Section 1: Identification

**Product Name:** ClōSYS Sulfate-Free Fluoride Toothpaste

**Synonyms:** Sodium Fluoride and Sodium Chlorite Dentifrice

**CAS Number:** 7681-49-4, 7758-19-2

**Product Use:** Intended for use by humans as an over-the-counter cosmetic drug to aid in the prevention of dental cavities.

**Manufacturer/Supplier:** Rowpar Pharmaceuticals, Inc.

**Address:** 16100 N Greenway Hayden Loop, Suite 400, Scottsdale, AZ 85260, USA

**General Information:** (480) 948-6997 or (800) 643-3337

**Transportation Emergency Number:** Not Applicable

### Section 2: Hazard(s) Identification

#### GHS Classification:

Health	Environmental	Physical
Acute Toxicity - Category 5 Eye Corrosion - Category 2 Skin Corrosion - Category 3 Skin Sensitization - Category 3 Mutagenicity - None Carcinogenicity - None Reproductive/Developmental – None Target Organ Toxicity (Repeated) – None	Aquatic Toxicity – Category IV	Flammable Liquid - No

#### GHS Label:

##### Symbols:

##### **Hazard Statements**

This product is a sodium fluoride dentifrice, which is classified as a drug by the United States Food and Drug Administration (FDA). Please refer to the **Drug Facts** on product packaging (label) for detailed information about warnings and directions for use.

##### **Precautionary Statements**

This product rarely presents a problem when used according to directions. It is safe for its intended use. As with all consumer products, individuals may have allergic from skin contact, such as temporary change in taste sensation, redness, rash and/or swelling.

This product is not intended for ingestion or consumption. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

### Section 3: Composition/Information on Ingredients

Component	CAS Number	Weight %
Purified Water	7732-18-5	Proprietary
Hydrated Silica	Proprietary	Proprietary
Sorbitol	50-70-4	Proprietary
Cellulose Gum	Proprietary	Proprietary
Dibasic Sodium Phosphate	7558-79-4	Proprietary
Titanium Dioxide	13463-67-7	Proprietary
Flavor	Proprietary	Proprietary
Sodium Fluoride	7681-49-4	0.240
Sodium Chlorite	7758-19-2	0.125
Monobasic Sodium Phosphate	7558-80-7	Proprietary
Sucralose	56038-13-2	Proprietary
(See Section 8 for Exposure Limits)		

### Section 4: First-Aid Measures

The procedures in this section are recommended as emergency first aid only. This information is not intended to replace or supplant treatment advice from a health-care professional.

**General Advice:** If reaction to the product does not subside quickly (within a few minutes), immediately consult physician.

**Skin Contact:** Flush with copious amounts of water.

**Eye Contact:** Flush with copious amounts of water.

**Inhalation:** Not applicable

In the event an adverse drug reaction occurs, please seek immediate medical attention and discontinue use of product. Also, please notify Manufacturer.

### Section 5: Fire-Fighting Measures

#### FLAMMABLE PROPERTIES

Flammable	No
Combustible	No
Flash Point	Not Applicable
Flammable Limits	Not Applicable
Contents under Pressure	No
Extinguishing Media	Not Applicable
Special Fire Procedures	Not a fire hazard

<b>Explosive</b>	No
<b>Section 6: Accidental Release Measures</b>	
<b>Spill or Leak Procedure</b>	
For minor spills of product, proceed with routine clean-up with water. Large spills of product should be collected in a suitable container.	
<b>Section 7: Handling and Storage</b>	
<b>Handling</b>	
Use product only as directed on product packaging. Avoid contact with skin and eyes. Do not ingest.	
<b>Product Storage</b>	
For maximum product effectiveness, store in a dry area at room temperature and keep contents of product tightly closed and stored in the original container. Avoid storing at high temperatures or near a heat source. Avoid freezing temperatures.	
<b>Container Information</b>	
<b>Pressured Container</b>	No
<b>Container Type</b>	Glamine Tube
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Respiratory Protection</b>	None
<b>Eye/Face Protection</b>	None
<b>Skin Protection</b>	None
<b>Special Storage Required</b>	None
<b>Section 9: Physical and Chemical Properties</b>	
<b>Odor</b>	Slight Mint
<b>Color</b>	White
<b>General Physical Form</b>	Paste (Semi-solid)
<b>Flash Point</b>	Not Applicable
<b>Evaporation Rate</b>	Not Determined
<b>Solubility in Water</b>	Not Determined
<b>Boiling Point</b>	Not Determined

<b>Vapor Density</b>	Not Determined
<b>Vapor Pressure</b>	Not Determined
<b>Specific Gravity</b>	1.230 – 1.260
<b>pH</b>	6.5 – 7.5
<b>Melting Point</b>	Not Determined

## Section 10: Stability and Reactivity

<b>Chemical Stability</b>	Stable
<b>Materials to Avoid</b>	None
<b>Special Conditions to Avoid:</b> Avoid storing or exposing product to extreme heat or sun. Avoid storing or exposing product to freezing temperatures. Avoid directly exposing product to light (ultraviolet or visible). Avoid storing or exposing product to highly humid conditions.	
<b>Hazardous Reaction and</b>	
<b>Decomposition Products</b>	None
<b>Corrosive</b>	No

## Section 11: Toxicological Information

### Animal Toxicology, Mutagenicity, Reproductive/Developmental Toxicity

No formal toxicology studies are available for product. Refer to the following references for toxicological information related to chlorite and fluoride:

1. Lubbers JR, Bianchine JR. Effects of the acute rising dose administration of chlorine dioxide, chlorate, and chlorite to normal healthy adult male volunteers. *J Environ Pathol Toxicol Oncol.* 1984. Jul;5(4-5):215-28.
2. US Department of Health and Human Services. Toxicological profile of chlorine dioxide and chlorite. 2004. Available at: <http://www.atsdr.cdc.gov/ToxProfiles/tp160.pdf>
3. US Environmental Protection Agency. Toxicological review of chlorine dioxide and chlorite. 2000. Available at: <http://www.epa.gov/iris/toxreviews/0496tr.pdf>
4. US Department of Health and Human Services. Toxicological profile of fluorides, hydrogen fluoride, and fluorine. 2003. Available at: <http://www.atsdr.cdc.gov/ToxProfiles/tp11.pdf>

### Carcinogenicity

None

## Section 12: Ecological Information

### Ecotoxicological Information

Not available

## Section 13: Disposal Considerations

### Container Disposal

Dispose of container in trash.

### Disposal Procedure

Dispose product in accordance with all applicable local, state and federal regulations.

## Section 14: Transport Information

### DOT Classification

Not Applicable

## Section 15: Regulatory Information

### US Federal Regulations

**US Food and Drug Administration (FDA):** Product is regulated as an over-the-counter drug under US CFR Title 21 Part 310, 369, and 355 Anticaries Drug Products for Over-The-Counter Human Use (Final Monograph). Product is therefore subject to all applicable US Federal Regulations that ensure general recognition of safety and effectiveness of drug products.

### State Laws

**California:** The California Safe Cosmetics Act of 2005 requires cosmetic manufacturers to disclose to the California Department of Public Health all cosmetic products containing titanium dioxide and hydrated silica, among other chemicals. This product contains titanium dioxide and hydrated silica.

## Section 16: Other Information

**Revision Date:** June 17, 2014

**Supersedes:** March 1, 2012 MSDS Document for *ClōSYS* Sulfate-Free Fluoride Toothpaste

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