



Safety Data Sheet

Section 1: Identification

Product Name: *ClōSYS* Alcohol-Free Fluoride Rinse
Synonyms: Sodium Fluoride and Sodium Chlorite Solution
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, to eliminate oral malodor, and to cleanse the oral cavity.
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:	
<p>Hazard Statements</p> <p>This product contains sodium fluoride, 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.</p>	<p>Precautionary Statements</p> <p>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 reaction from skin contact, such as temporary change in taste sensation, redness, rash, and/or swelling. Eye contact may produce temporary irritation.</p> <p>This product is not intended for ingestion or consumption. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.</p>

Section 3: Composition/Information on Ingredients

Component	CAS Number	Weight %

Purified Water	7732-18-5	Proprietary
Sodium Fluoride	7681-49-4	0.05
Trisodium Phosphate	7601-54-9, 10101-89-0	Proprietary
Sodium Chlorite	7758-19-2	0.100
Citric Acid	77-92-9, 5949-29-1	Proprietary
Flavor	Not Applicable	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
Explosive	No

Section 6: Accidental Release Measures

Spill or Leak Procedure

For minor spills of product, proceed with routine clean-up with water. Large spills of product should be collected in a suitable container, and the surface should be cleaned up with water.

Section 7: Handling and Storage

Handling

Use product only as directed on product packaging (label). Avoid contact with skin and eyes. Do not ingest.

Product Storage

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.

Container Information

Pressured Container	No
Container Type	High Density Polyethylene (HDPE) Bottle

Section 8: Exposure Controls/Personal Protection

Respiratory Protection	None
Eye/Face Protection	None
Skin Protection	None
Special Storage Required	None

Section 9: Physical and Chemical Properties

Odor	Light Mint
Color	None (colorless)
General Physical Form	Liquid
Flash Point	Not Applicable
Evaporation Rate	Not Determined
Solubility in Water	Completely Miscible
Boiling Point	Not Determined
Vapor Density	Not Determined
Vapor Pressure	Not Determined
Specific Gravity	Not Determined
pH	6.90 – 7.40 (Room Temperature)
Melting Point	Not Determined

Section 10: Stability and Reactivity

Chemical Stability Stable

Materials to Avoid None

Special Conditions to Avoid: 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.

Hazardous Reaction and

Decomposition Products None

Corrosive No

Section 11: Toxicological Information

Animal Toxicology, Mutagenicity, Reproductive/Developmental Toxicity

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

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 through recycling or trash.

Disposal Procedure

Dispose of 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: Product is not regulated under the provisions of Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986).

Section 16: Other Information

Revision Date: Original Version (February 10, 2016)

Supersedes: None

Disclaimer: Information presented herein has been compiled from sources considered by the Manufacturer, in good faith, to be dependable and is accurate and reliable to the best of our knowledge and belief. However, Manufacturer cannot make any warranty or representation respecting the accuracy or completeness of the data and assumes no responsibility for any liability or damages relating thereto or for advising you regarding the protection of your employees, customers or others. Users should make their own tests to determine the applicability of such information or suitability of any products for specific use.