

MATERIAL SAFETY DATA SHEET

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	CiSYS Sulfate-Free Fluoride Toothpaste
Product Use	Intended for use by humans as an over-the-counter cosmetic drug to aid in the prevention of dental cavities.
Manufacturer Name	Rowpar Pharmaceuticals, Inc.
Manufacturer Address	16100 N Greenway Hayden Loop, Suite 400 Scottsdale, AZ 85260 USA
Emergency Telephone Number	(480) 948-6997 or (800) 643-3337
Effective Date	March 1, 2012
Last Changed	March 1, 2012
Supersedes	October 26, 2011 MSDS Document for CiSYS Sulfate-Free Fluoride Toothpaste

This sheet has been prepared in accordance with the requirements of the United States Federal OSHA Hazard Communications Standard, 29 CFR 1910.1200.

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

<u>Chemical Name</u>	<u>C.A.S. No.</u>	<u>% by Weight</u>
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

SECTION 3. HAZARDS IDENTIFICATION**Emergency Overview**

White, smooth, slight mint paste.

Potential Health Effects

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 reactions such as redness, rash and/or swelling.

Accidental Ingestion

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.

Hazardous Components

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.

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.

SECTION 7. HANDLING AND STORAGE**Handling**

Use product only as directed on product packaging. 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	Glamine Tube

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	Slight mint
Color	White
General Physical Form	Paste (Semi-solid)
Flash Point	Not Applicable
Evaporation Rate	Not Determined
Solubility in Water	Not Determined
Boiling Point	Not Determined
Vapor Density	Not Determined
Vapor Pressure	Not Determined
Specific Gravity	1.230 – 1.260
pH	6.5 – 7.5
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 product. Refer to the following references for toxicological information related to chlorite and fluoride. These references justify the classification as non-toxic.

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

SECTION 14. TRANSPORT INFORMATION

DOT Classification

Class 85

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, 355, and 369 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.

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.

MATERIAL SAFETY DATA SHEET

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	ClōSYS Alcohol-Free Oral Health Rinse
Product Use	Intended for cosmetic use as a mouthwash in humans, to eliminate oral malodor and to cleanse the oral cavity.
Manufacturer Name	Rowpar Pharmaceuticals, Inc.
Manufacturer Address	16100 N Greenway Hayden Loop, Suite 400 Scottsdale, AZ 85260, USA
Emergency Telephone Number	(480) 948-6997 or (800) 643-3337
Prepared By	Rowpar Pharmaceuticals, Inc.
Effective Date	March 1, 2012
Last Changed	March 1, 2012
Supersedes	March 24, 2011 MSDS Document for ClōSYS Oral Rinse

This sheet has been prepared in accordance with the requirements of the United States Federal OSHA Hazard Communications Standard, 29 CFR 1910.1200.

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

<u>Chemical Name</u>	<u>C.A.S. No.</u>	<u>% by Weight</u>
Purified Water	7732-18-5	Proprietary
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

SECTION 3. HAZARDS IDENTIFICATION

Emergency Overview

Clear, odorless liquid.

Potential Health Effects

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

reactions from skin contact, such as temporary change in taste sensation, redness, rash and/or swelling. Eye contact may produce temporary irritation.

Accidental Ingestion

No acute or chronic hazards (non-toxic). The product is not intended for ingestion or consumption.

Hazardous Components

None

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	None (odorless)
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	1.00 – 1.01 (Room Temperature)

pH	6.4 – 7.0 (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. These references justify the classification as non-toxic.

1. Lubbers JR, Blanchine 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>

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

Non-flammable toiletries

SECTION 15. REGULATORY INFORMATION

US Federal Regulations

US Food and Drug Administration (FDA): Product is regulated as a cosmetic under US Code, Title 21, Federal Food, Drug, and Cosmetic Act.

State Laws

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

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.