MATERIAL SAFETY DATA SHEET

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name *CloSYS* 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 24, 2011

Last Changed March 24, 2011

Supersedes None

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

Chemical Name	C.A.S. No.	% by Weight
Water	Not Applicable	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, minty paste.

Potential Health Effects

Product rarely presents a problem when used according to directions. This product 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

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	Glaminate 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	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	1.24 – 1.27
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:

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 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 of 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.