

Safety Data Sheet

Section 1: Identification

Product Name: ClōSYS Alcohol-Free Oral Health Rinse

Synonyms: Sodium Chlorite Solution

CAS Number: 7758-19-2

Product Use: Intended for cosmetic use as a mouthwash in humans, 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	Aquatic Toxicity - Category IV	Flammable Liquid - No
Eye Corrosion - Category 2		
Skin Corrosion - Category 3		
Skin Sensitization - Category 3		
Mutagenicity - None		
Carcinogenicity - None		
Reproductive/Developmental – None		
Target Organ Toxicity (Repeated) - None		

GHS Label:

Symbols:	
Hazard Statements No acute or chronic hazards (non-toxic).	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. Eye contact may produce temporary irritation.
	This product is not intended for ingestion or consumption.

Section 3: Composition/Information on Ingredients

Component	CAS Number	Weight %
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
(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 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:

- Lubbers JR, Bianchine JR. Effects of the acute rising dose administration of chlorine dioxide, chlorate, and chlorite to normal healthy adult male volunteers. <u>J Environ Pathol Toxicol Oncol.</u> 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 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 a cosmetic under the Federal Food, Drug, and Cosmetic Act, and by the corresponding regulations in 21 CFR.

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: June 17, 2014

Supersedes: March 1, 2012 MSDS Document for *ClōSYS* Alcohol-Free Oral Health Rinse

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 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.



Safety Data Sheet

Section 1: Identification

Product Name: Flavor Control™ for ClōSYS Alcohol-Free Oral Health Rinse

Synonyms: Peppermint oil **CAS Number:** 8006-90-4

Product Use: Intended to add mint flavor to *ClōSYS* Alcohol-Free Oral Health Rinse. *ClōSYS* Alcohol-Free Oral Health Rinse is intended for cosmetic use as a mouthwash in humans, 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	Aquatic Toxicity – Category IV	Flammable Liquid - No
Eye Corrosion - Category 2		
Skin Corrosion - Category 3		
Skin Sensitization - Category 3		
Mutagenicity - None		
Carcinogenicity - None		
Reproductive/Developmental – None		
Target Organ Toxicity (Repeated) - None		

GHS Label:

Symbols:			
Hazard Statements Precautionary Statements			
	Product may cause irritation to skin and eyes. Vapors from product may cause irritation to throat and lungs. Inhalation of high concentrations of vapor may result in anesthetic effects. Repetitive contact with product may result in allergic dermatitis.		
	This product is not intended for ingestion or consumption. Potentially hazardous if ingested in large quantities.		

Section 3: Composition/Information on Ingredients

Component	CAS Number	Weight %
Mineral Oil	8042-47-5	Proprietary
Essential Peppermint Oil	8006-90-4	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: Remove contaminated clothing and wash with soap and water.

Eye Contact: Flush with water for 15 minutes.

Inhalation: Remove to fresh air.

Ingestion: Drink milk or water to dilute, contact poison control.

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

This section refers particularly to quantities greater than found in a single consumer size of $Cl\bar{o}SYS$ Flavor ControlTM.

FLAMMABLE PROPERTIES

Autoignition Temperature Not Available

Flash Point 165.2°F

Flammable Limits – LEL Not Available

Flammable Limits – UEL Not Available

Extinguishing Media

Foam, Carbon Dioxide (CO₂), Dry Chemical

Special Firefighting Procedures/Unusual Fire and Explosive Hazards

None known. Use self contained breathing apparatus and protective clothing.

Note: See STABILITY AND REACTIVITY (SECTION 10) for hazardous combustion and thermal decomposition information.

Section 6: Accidental Release Measures

Spill or Leak Procedure

Eliminate flames and sources of ignition. Wipe up small spills with a cloth. For larger spills, use porous absorbent.

Section 7: Handling and Storage

Handling

Handle according to good safety procedures and avoid unnecessary exposure.

Product Storage

Store product in original, sealed container. Keep product away from heat, light, direct sunlight, and sources of ignition. Store product in cool area (moderate temperatures 60-80°F).

Container Information

Pressured Container No

Container Type High Density Polyethylene (HDPE) Bottle

Section 8: Exposure Controls/Personal Protection

This section refers particularly to quantities greater than found in a single consumer size of $Cl\bar{o}SYS$ Flavor ControlTM.

Respiratory Protection Not usually necessary, but approved respirator can be used if

desired.

Eye/Face Protection Splash goggles

Protective Gloves Chemical resistant

Ventilation RecommendedLocalized exhaust can be used to remove vapors.

Other Protective Equipment Eye wash station and safety shower recommended in area.

Section 9: Physical and Chemical Properties

Odor Strong mint

Color Colorless

General Physical Form Liquid

Flash Point 165.2°F

Evaporation Rate Not Determined

Solubility in Water Insoluble

Boiling Point Not Determined

Vapor Density Not Determined

Vapor Pressure Not Determined

Specific Gravity Proprietary

Refractive Index Proprietary

pH Not Determined

Melting Point Not Determined

Section 10: Stability and Reactivity

Chemical Stability

Stable

Materials and Conditions to Avoid

Avoid interaction of product with strong oxidizing chemicals. Avoid heat and flame. Avoid elevated temperatures above 60°C.

Hazardous Combustion/Decomposition Product

Burning produces carbon monoxide and carbon dioxide.

Hazardous Polymerization Product

Hazardous polymerization will not occur.

Section 11: Toxicological Information

Animal Toxicology, Mutagenicity, Reproductive/Developmental Toxicity

Not available

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 Not Applicable

Section 15: Regulatory Information

All ingredients have been inspected, and the finished product is in accordance with formulated Specifications for this material. It has been processed in accordance with Good Manufacturing Practices and prescribed standards of sanitation as practiced in the industry. All ingredients are generally recognized as safe (GRAS), approved by a regulation of the United States Food and Drug Administration (FDA) or appear on the industry-approved register of safe ingredients for the flavor industry.

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 mineral oil, among other chemicals. This product contains mineral oil.

Section 16: Other Information

Revision Date: June 17, 2014

Supersedes: March 24, 2011 MSDS Document for Flavor Control™ for ClōSYS Alcohol-Free Oral Health

Rinse

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 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.