

SAFETY DATA SHEET
KOLORZ PROPHYLAXIS PASTE WITH SODIUM FLUORIDE

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Issued: 09/04/2014
Revision No. 0
395786

SECTION 1: IDENTIFICATION

Product Name: KOLORZ PROPHYLAXIS PASTE WITH SODIUM FLUORIDE

Product Item Code(s): 188401, 188402, 188403, 188404, 188405, 188406, 188407, 188408, 188409, 188410, 188411, 188415, 188416, 188417, 788401, 788402, 788403, 788404, 788405, 788406, 788407, 788408, 788409, 788412, 788413, 788415, 788416, 788417.

Recommended Use: Dental cleaning and polishing. Dental Prophylaxis treatment.

Restrictions on Use: Do not swallow. For use by dental professional only.

Company Name: DMG America, LLC
242 South Dean ST.
Englewood, NJ 07631

Information Telephone Number: 201-894-5500

Emergency Telephone Number: 1-800-535-5053 (Infotrac)

SECTION 2: HAZARD(S) IDENTIFICATION

Emergency Overview

- Direct contact may cause eye irritation.
- Prolonged skin contact may cause irritation.
- Ingestion of large amounts may be harmful.



Irritant
Harmful

Potential Health Effects:

Eyes: Direct contact may cause irritation with redness.

Skin: Prolonged skin contact may cause irritation.

Inhalation: No adverse effects expected.

Ingestion: May cause salivation, nausea, vomiting. Ingestion of large quantities may cause abdominal pain, headaches, nausea or dizziness.

Chronic Health Effects: Repeated overexposure to sodium fluoride may cause fluorosis. Not expected under normal conditions of use.

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin disease may be at increased risk from exposure.

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EU Preparation Classification (1272/2008/CLP): Irritant, Harmful.

OSHA Classification: Regulated as a medical device. Irritant, Harmful.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No./ EINECS No.	Percent (By Weight)	Substance Classification (67/548/EEC) and 1272/2008/CLP
Glycerin	56-81-5/ 200-289-5	25-45%	R36/38, H319, H315
Sodium Fluoride	7681-49-4/231-667-8	1-3%	[T]R25,R32,R36/38 and H301, H315, H319, EUH032
Sodium Silicate	1344-09-8/215-687-4	1-5%	[Xi]R36/38, H319, H315
Phosphoric Acid	7664-38-2/231-633-2	1-3%	[C]R34, H314

See Section 16 for further information on R and H Phrases.

SECTION 4: FIRST AID MEASURES

Eye Contact: Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation develops or persists.

Skin Contact: Wash skin with plenty of soap and water. Get medical attention if irritation develops.

Ingestion: Do not induce vomiting. If conscious, rinse out mouth with water and give copious amount of milk, or water if milk is not available. Never give anything by mouth to an unconscious person. If symptoms persist, get immediate medical attention.

Inhalation: Move victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if irritation persists.

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing Media: Use media appropriate for surrounding fire. Use water spray to cool containers.

Firefighting Procedures: Firefighters should wear full emergency equipment and positive pressure self-contained breathing apparatus.

Unusual Fire/Explosion Hazards: None known.

Known or Anticipated Hazardous Products of Combustion: Carbon monoxide, carbon dioxide and toxic fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Accidental Release Measures: Wear appropriate protective clothing as described in Section 8. Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Prevent spill from entering sewers and water courses. Report releases as required by local, state and federal authorities.

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Personal Precautions: Avoid contact with eyes and prolonged skin contact.

Environmental Precautions: Do not allow to enter waterways or sewers.

SECTION 7: HANDLING AND STORAGE

Handling: Avoid contact with the eyes and prolonged skin contact. Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all MSDS precautions when handling empty containers.

Storage: Store in a cool, dry, well-ventilated area. Do not store above 30°C (86°F). Keep out of direct sunlight.

SECTION 8: EXPOSURE CONTROL/ PERSONAL PROTECTION

Occupational Exposure Limits:

Glycerin	5 mg/m ³ PEL (respirable fraction) 10 mg/m ³ TWA ACGIH
Sodium Fluoride (as Fluoride)	2.5 mg/m ³ ACGIH TLV TWA 2.5 mg/m ³ OSHA PEL TWA
Phosphoric Acid	1 mg/m ³ ACGIH TLV TWA 1 mg/m ³ OSHA PEL

Engineering Controls: No special ventilation normally required. For bulk handling, use ventilation that is adequate to maintain exposure levels below the occupational exposure limits.

Personal Protective Equipment:

Eye Protection: Safety glasses recommended for bulk handling.

Skin Protection: None required from normal use. Wear impervious gloves such as natural rubber if needed to for bulk handling.

Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded an approved respirator with particulate cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Other Protective Clothing or Equipment: None needed for normal use. Impervious clothing as needed to avoid contamination of personal clothing for bulk handling.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Paste in various colors and flavors. Characteristic odor.

Boiling Point: Not available

Evaporation Rate: Not available

Melting Point: Not available

Viscosity: Not applicable

Freezing Point: Not available

% Volatile by Volume: Not available

Specific Gravity: Not available

Solubility in Water: Slightly Soluble

Flashpoint: Not applicable

Vapor Pressure (mmHg): Not available

Flammable Limits in Air: LEL: N/A

Vapor Density: Not available

UEL: N/A

pH: 5-7

Autoignition Temperature: Not applicable

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable.

Conditions to Avoid (stability): None known.

Incompatibility with Other Materials: Avoid oxidizing agents and strong acids.

Hazardous Decomposition Products: May produce carbon monoxide, carbon dioxide and toxic fumes.

Hazardous Polymerization: Will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicological Data: Data not available for the product itself. The data provided are for the ingredients listed below:

Glycerin:	Oral rat LD ₅₀ : 12,600 mg/kg
	Skin rabbit LD ₅₀ : >10,000 mg/kg
	Inhalation rat LC ₅₀ : >570 mg/m ³ /1 hr.
Sodium Fluoride:	Oral rat LD ₅₀ : 52 mg/kg
Phosphoric acid:	Oral rat LD ₅₀ : 1530 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

Ecological data not available for the product itself. The data provided are for the ingredients listed below:

Glycerin:	96 hrs. LC ₅₀ fathead minnow: 44,000 mg/L
	96 hrs. LC ₅₀ goldfish: >5,000 mg/L
Sodium Fluoride:	96 hrs. LC ₅₀ fish: >100 mg/L

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

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SECTION 14: TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated
DOT Hazard Class: N/A
UN Number: N/A
DOT Labels Required (49CFR172.101): N/A
IATA Shipping Name: Not Regulated
IATA Hazard Class: N/A
UN Number: N/A
IATA Hazard Labels Required: N/A
IMDG Shipping Name: Not Regulated
IMDG Class: N/A
UN Number: N/A
IMDG Label: N/A

SECTION 15: REGULATORY INFORMATION

Hazard Symbols:



Irritant
Harmful

U.S. FEDERAL REGULATIONS:

SARA TITLE III:

Hazard Category for Section 311/312: Acute Health, Chronic Health

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements under SARA Title III, Section 313 (40 CFR 372): None at or above reportable quantity.

Section 302 extremely hazardous Substances (TPQ): None at or above reportable quantity

EPA Toxic Substances Control Act (TSCA) Status: This product is a medical device and not subject to chemical notification requirements.

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions.

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SECTION 16: OTHER INFORMATION

Risk phrases used in Section 3:

- R25 (H301): Toxic if swallowed.
- R32 (EUH032): Contact with acids liberates very toxic gas.
- R34: Causes burns.
- R36/38: Irritating to eyes and skin.
- H315: Causes skin irritation.
- H319: Causes serious eye irritation.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.
