

**SAFETY DATA SHEET**  
**KOLORZ PROPHYLAXIS PASTE WITH SODIUM FLUORIDE**

Page 1 of 6  
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.

**SAFETY DATA SHEET**  
**KOLORZ PROPHYLAXIS PASTE WITH SODIUM FLUORIDE**

Page 2 of 6  
Issued: 09/04/2014  
Revision No. 0  
395786

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.

**SAFETY DATA SHEET**  
**KOLORZ PROPHYLAXIS PASTE WITH SODIUM FLUORIDE**

Page 3 of 6  
Issued: 09/04/2014  
Revision No. 0  
395786

**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 <sup>3</sup> PEL (respirable fraction) 10 mg/m <sup>3</sup> TWA ACGIH
Sodium Fluoride (as Fluoride)	2.5 mg/m <sup>3</sup> ACGIH TLV TWA 2.5 mg/m <sup>3</sup> OSHA PEL TWA
Phosphoric Acid	1 mg/m <sup>3</sup> ACGIH TLV TWA 1 mg/m <sup>3</sup> 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.

**SAFETY DATA SHEET**  
**KOLORZ PROPHYLAXIS PASTE WITH SODIUM FLUORIDE**

Page 4 of 6  
Issued: 09/04/2014  
Revision No. 0  
395786

**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 <sub>50</sub> : 12,600 mg/kg
	Skin rabbit LD <sub>50</sub> : >10,000 mg/kg
	Inhalation rat LC <sub>50</sub> : >570 mg/m <sup>3</sup> /1 hr.
Sodium Fluoride:	Oral rat LD <sub>50</sub> : 52 mg/kg
Phosphoric acid:	Oral rat LD <sub>50</sub> : 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 <sub>50</sub> fathead minnow: 44,000 mg/L
	96 hrs. LC <sub>50</sub> goldfish: >5,000 mg/L
Sodium Fluoride:	96 hrs. LC <sub>50</sub> fish: >100 mg/L

**SECTION 13: DISPOSAL CONSIDERATIONS**

Dispose in accordance with national and local regulations.

**SAFETY DATA SHEET**  
**KOLORZ PROPHYLAXIS PASTE WITH SODIUM FLUORIDE**

Page 5 of 6  
Issued: 09/04/2014  
Revision No. 0  
395786

**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.

