



Safety Data Sheet

Document Number: RM013

Date Revised: 07/May/2014

Revision Number: C

1. PRODUCT IDENTIFICATION

Trade Name (as labeled): NEXT® Prophylaxis Paste with Fluoride

Chemical Name/Classification: Mixture

Product Identifier (Part/Item Number): 220013, 220023, 220033, 220043, 220053, 220063, 220073, 220083, 220103, 220113, 220123, 220133, 220143, 220153, 220163, 220173, 220183, 220193, 220203, 220213, 220223, 220233, 220243, 220253, 220263, 220273, 220283, 220293, 220303, 220313, 220323, 220333, 220343, 221113, 221123, 221133, 221143, 221153, 221163,

U.N. Number: None

U.N. Dangerous Goods Classification: None

Recommended Use: Cleaning and polishing paste used during dental hygiene procedures

Restrictions on Use: For professional dental use only

Manufacturer/Supplier Name: Preventive Technologies, Inc. (www.preventech.com)

Manufacturer/Supplier Address: 4330C Matthews-Indian Trail Road
Indian Trail, NC 28079

Manufacturer/Supplier Telephone Number: 1-704-849-2416 or 1-800-474-8681 (Product Information)

Email address: customerservice@preventech.com

2. HAZARD(s) IDENTIFICATION

| Health | Environmental | Physical |
|---------------------------|---------------|---------------|
| Acute Toxicity Category 4 | Non-Hazardous | Non-Hazardous |

Emergency Overview: Direct contact may cause eye irritation. Prolonged skin contact may cause irritation May be harmful if swallowed. Under normal conditions of use, exposure is not expected to occur.

EU Classification(1999/45/EC: Not Classified

| Hazard Statement | Precautionary Statement |
|---------------------------|---|
| H302 Harmful if swallowed | P264 Wash exposed skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product P301 + P312: May be harmful is contents are swallowed P330 Rinse mouth P501 Dispose of contents and container in accordance with Local and national regulations |

Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

| Ingredient | CAS No. / EINECS No. | Percent | EC Substance Classification (67/548/EEC) |
|-----------------|------------------------|---------|---|
| Pumice | 1332-09-8 | 30-50 | Not Applicable |
| Glycerin | 56-81-5 / 200-289-5 | 25-45 | Not Applicable |
| Sodium Fluoride | 7681-49-4 / 231-667- 8 | 2.7 | T, R25, R32, R36/38 Acute Toxicity: 3, H301 Eye Irritation: 2, H319 Skin Irritation: 2, H315 |





Refer to Section 16 for the full text of the EU Classifications and R Phrases.

4. FIRST-AID MEASURES

| Routes of Exposure | First Aid Instructions |
|--------------------|---|
| Eye | Flush eyes with large quantities of water several minutes, holding the eyelids apart. Get medical attention if irritation develops or persists. |



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| Skin | No first aid should be needed. Rinse off with water. Get medical attention if irritation develops. |
| Inhalation | None needed under normal use conditions. |
| Ingestion | If over normal dose is swallowed, DO NOT induce vomiting. Drink large quantities of water, milk or several ounces of milk of magnesia. Contact poison control. |
| Most important symptoms of exposure | May cause mild eye irritation. May be harmful if large amounts are swallowed. |
| Other | None known. |
| Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions. | |

5. FIRE-FIGHTING MEASURES

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|---|---|--|---|
| Suitable Extinguishing Media: | Use media appropriate for surrounding fire. | | |
| Fire Fighting Procedures: | Cool fire exposed containers and structures with water. | | |
| Specific Hazards Arising from the Chemical: | None known. | | |
| Precautions for Fire Fighters: | Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. | | |
| Recommended Protective Equipment for Fire Fighters: | | | |
| EYES/FACE | SKIN | RESPIRATORY | THERMAL |
|  |  |  |  |

6. ACCIDENTAL RELEASE MEASURES

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|---|
| Personal Precautions, PPE and Emergency Procedures: Small spills do not require special precautions. |
| Environmental Precautions: None needed |
| Methods and Materials for Containment and Clean-up: Wear appropriate protective clothing as described in Section 8. Wipe up or collect using absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Prevent spill from entering sewers and water sources. Report release as required by local, state and federal authorities. |

| Recommended Personal Protective Equipment for Containment and Clean-up: | | | |
|---|---|-------------|---------|
| EYES/FACE | SKIN | RESPIRATORY | THERMAL |
|  |  | | |

7. HANDLING AND STORAGE

Precautions for Safe Handling: Use in accordance with package instructions. Avoid contact with eyes and prolonged skin contact. Wash thoroughly with soap and water after handling. Do not reuse containers.

Conditions for Safe Storage: Store in a cool, dry well ventilated area. Keep out of direct sunlight


8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

| Ingredient | Exposure Limits |
|-------------------------------|---|
| Pumice | None Established |
| Glycerin | 5 mg/m ³ TWA PEL (respirable fraction) 10 mg/m ³ TWA TLV |
| Sodium Fluoride (as Fluoride) | 2.5 mg/m ³ ACGIH TLV TWA 2.5 mg/M ³ OSHA PEL TWA 1 mg/m ³ Skin DFG MAK 2.5 mg/m ³ UK WEL |
| | |

Biological Exposure Limits:

Sodium Fluoride (as fluorides) -Prior to shift 3 mg/g creatinine; End of shift 10 mg/g creatinine

| | | | |
|--|------|-------------|---------|
| Appropriate Engineering Controls: No special controls required. | | | |
| Individual Protection Measures (PPE) Specific Eye/face Protection: Safety glasses should be worn if contact is likely. Specific Skin Protection: None normally required. Specific Respiratory Protection: None required under normal use conditions. Specific Thermal Hazards: Not applicable | | | |
| Recommended Personal Protective Equipment: | | | |
| EYES/FACE | SKIN | RESPIRATORY | THERMAL |
|  | | | |
| Environmental Exposure Controls: None required for normal use. | | | |
| General Hygiene Considerations and Work Practices: Routine hand washing after use recommended. | | | |
| Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product. | | | |

9. PHYSICAL AND CHEMICAL PROPERTIES

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|--------------------------------|--------------------------|--------------------------|----------------|
| Appearance: | Colored paste | Explosive limits: | Not applicable |
| Odor: | Characteristic of flavor | Vapor pressure: | Not available |
| Odor threshold: | Not available | Vapor density: | Not available |
| pH: | 9.00 – 10.50 | Relative density: | Not available |
| Melting/freezing point: | Not available | Solubility: | Insoluble |

| | | | |
|---|---------------|---|---------------|
| Initial boiling point and range: | Not available | Partition coefficient:n-octanol/water: | Not available |
| Flash point: | None | Auto-ignition temperature: | Not available |
| Evaporation rate: | Not available | Decomposition temperature: | Not available |
| Flammability: | Not flammable | Viscosity: | Not available |
| Explosive Properties: | None | Oxidizing Properties: | None |

10. STABILITY AND REACTIVITY

Reactivity: Not reactive.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous Decomposition Products: Thermal decomposition may produce carbon and sodium oxides and hydrogen fluoride.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Direct contact may cause mild irritation with redness and tearing. Glycerin is slightly irritating to rabbit eyes.

Skin: No adverse effects are expected. Glycerin is not irritating to rabbit or human skin.

Ingestion: Swallowing may cause nausea, vomiting and diarrhea. Large doses of fluorides can bind with serum calcium resulting in hypocalcaemia with toxic effects, including cardiac effects, due to electrolyte imbalance.

Inhalation: None expected from normal use.

Chronic Health Effects: Prolonged overexposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel.

Carcinogenicity: A 2-year study in rats found a weak, equivocal fluoride-related increase in the occurrence of osteosarcomas in male rats, and no evidence of carcinogenicity in female rats or male or female mice. The weight of the evidence indicates that fluoridation of water does not increase the risk of developing cancer. IARC has determined that the carcinogenicity of fluoride to humans is not classifiable.

None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NIP or EU Directives.

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| <p>Mutagenicity: Sodium fluoride was negative in the AMES test but was positive in a mouse lymphoma cells assay. Sodium fluoride did not induce DNA strand breaks in testicular cells of rats treated in vivo and did not cause chromosomal aberrations in bone marrow or testicular cells or sister chromatid exchanges in bone marrow cells of mice treated in vivo. Glycerin was negative in AMES test, in vitro sister chromatid exchange and unscheduled DNA synthesis. Propylene glycol: In-vitro studies were negative</p> |
| <p>Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.</p> |
| <p>Acute Toxicity Data: Glycerin: Oral Rat LD50 >12,600 mg/kg Sodium Fluoride: Oral Rat LD50 32mg/kg</p> |
| <p>Reproductive Toxicity Data: Sodium Fluoride: In a 75 day reproductive study with rats, doses of 4.5 ppm and 9.0 ppm showed a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity. At doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found. Glycerin: No effects were observed in a 2 generation study at doses of 0.2 mg/kg/day. No developmental effects were observed in rabbits administered up to 1,180 mg/kg or in rats or mice administered up to 1,310 mg/kg.</p> |
| <p>Specific Target Organ Toxicity (STOT): <u>Single Exposure:</u> Sodium Fluoride: In a human exposure study, adults were given 250 mg. Effects included nausea, vomiting, epigastric distress, salivation and itching of the hands and feet. In an acute study, dogs were infused with an acute dose of 36 mg/kg. Death occurred in less than 65 minutes. Principal effects included a decline in blood pressure, heart rate, central nervous system activity, vomiting and defecation. When placed into the eye of a rabbit, glycerin will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells. <u>Repeated Exposure:</u> Sodium Fluoride: Brain, liver, kidney and muscles demonstrate significant changes in essential trace element levels in adult female mice given 30, 60 and 120 ppm sodium fluoride in drinking water. Rats exposed to sodium fluoride in drinking water for 2 months developed thyroid effects; LOAEL 0.5 mg/kg/day. Mice exposed to sodium fluoride in drinking water for 4 weeks showed increased bone formation. LOAEL 0.8 mg/kg/day. In a 13 week sub-chronic inhalation study with rats, glycerin was found to cause mild irritation of mucous membranes. In a 2 year study in rats, no adverse effects were found in animals with 20% glycerin in their feed.</p> |

12. ECOLOGICAL INFORMATION

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| <p>Toxicity: Glycerin: 96 hr LC50 <i>Oncorhynchus mykiss</i> (Rainbow trout) 54,000 mg/L, 48 hr EC50 <i>daphnia magna</i> 10,000 mg/L Sodium Fluoride: 96 hr LC50 <i>Oncorhynchus mykiss</i> (Rainbow trout) 83.7 mg/L, 48 hr EC50 <i>daphnia magna</i> 98 mg/L Pumice: No data available</p> |
| <p>Persistence and Degradability: Glycerin is readily biodegradable (63% after 14 days). Biodegradation is not applicable to inorganic substances such as sodium fluoride.</p> |
| <p>Bio-accumulative Potential: No data is available to evaluate the potential for bioaccumulation of components of this product.</p> |
| <p>Mobility in Soil: Glycerin: Very high mobility in soil.</p> |
| <p>Other Adverse Effects: None known.</p> |

Results of PBT/vPvB Assessment: Not required.

13.DISPOSAL CONSIDERATIONS

Regulations:Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal:None known.

Waste Treatment Recommendations: None needed for normal anticipated use.

14.TRANSPORT INFORMATION

| | | | | |
|-----------------------------------|--|------------------------------|------------|-----------|
| UN-Number | ADR/RID: None | IMDG: None | IATA: None | DOT: None |
| UN proper shipping name | ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated | | | |
| Transport hazard class(es) | ADR/RID: None | IMDG: None | IATA: None | DOT: None |
| Packaging group | ADR/RID: None | IMDG: None | IATA: None | DOT: None |
| Environmental hazards | ADR/RID: No | IMDG Marine pollutant: No | IATA: No | DOT:No |

Special precautions for user: Not applicable

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has an RQ of 37,000 lbs based on the RQ of sodium fluoride of 1,000 lbs present at 2.7%. Many other states have more stringent regulations. Report all spills in accordance with local, state, and federal regulations.

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

Clean Water Act (CWA):Not Listed

Clean Air Act (CAA):Not Listed

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

| | | | |
|--------------------------|------------|---------------------------|-----------|
| Immediate Hazard: | Yes | Pressure Hazard: | No |
| Delayed Hazard: | No | Reactivity Hazard: | No |
| Fire Hazard: | No | | |

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

| Components | C.A.S. # | WT % |
|------------|----------|------|
| None | | |

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm: None

International Regulations

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification Requirements.

Canadian WHMIS Classification: Medical devices are not subject to WHMIS.

EU REACH: This product is a medicinal product and not subject to registration requirements.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

T Toxic

R25 Toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R36/38 Irritating to eyes and skin.

Acute Tox. 3 Acute Toxicity Category 3

Acute Tox. 4 Acute Toxicity Category 4

Skin Irrit. 2 Skin Irritation Category 2

Eye Irrit. 2 Eye Irritant Category 2

H301 Toxic if swallowed.

H302 Harmful if swallowed

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Date of SDS Preparation/Revision: 07 May 2014 Rev. C Supercedes: 01/2004 Rev. B

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.