

SAFETY DATA SHEETS

This SDS packet was issued with item:

074083184

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071194000 071194018 071194026 071194034 071194042 071194059 071194067 071194075 071194083 071194091
071194109 071194117 071194125 071194133 071194141 074082632 074082640 074082657 074082855 074082863
074082889 074082905 074082954 074082962 074082970 074082988 074083028 074083036 074083044 074083051
074083069 074083077 074083085 074083093 074083101 074083119 074083127 074083135 074083143 074083150
074083168 074083176 074083192 074083200 074083218 074083234 074083242 074083259 074083267 074083317
074083358 074083366

SAFETY DATA SHEET

SECTION 1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: NUPRO® Sensodyne® Prophylaxis Paste with Novamin®, with and without Fluoride
Product Number: 801510, 801511, 801512, 801513, 801514, 801515, 801516, 801517, 801518, 801519, 801520, 801524, 801525, 801526, 801527, 801528, 801529, 801530, 801531, 801531, 801532, 801533, 801534, 801535, 801536, 801537, 801538, 801539, 801540, 801541, 965661, 965662, 965663, 965664

MSDS Code Number: 801363

U.N. Number: N/A

U.N. Dangerous Goods Classification: N/A

Manufacturer: DENTSPLY Professional

Address: 1301 Smile Way
York, PA 17404

Information Telephone Number: 1-800-989-8826 or 717-767-8502

Emergency Telephone Number: 1-800-989-8826 or 717-767-8502

Email: ProfessionalMSDS@dentsply.com

Product Use: For cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment. Secondly, the product can be used for the immediate relief of tooth sensitivity, pre- and post-scaling and root planing.

Date of Last Revision: July 21, 2010

SECTION 2 HAZARDS IDENTIFICATION

Emergency Overview: Direct contact may cause eye irritation. Prolonged skin contact may cause irritation. May be harmful if swallowed. Contains crystalline silica. Prolonged overexposure to respirable crystalline silica may cause lung disease (silicosis) and increase the risk of lung cancer. The crystalline silica in this product is encapsulated in a viscous liquid. Under normal conditions of use, exposure is not expected to occur.

EU Preparation Classification (1999/45/EC): Not classified.

SECTION 3 COMPOSITION INFORMATION ON INGREDIENTS

| Ingredient | CAS No./EINECS No. | Percent | EC Substance Classification (67/548/EEC) |
|---|---------------------------|----------------|---|
| Glycerin | 56-81-5 / 200-289-5 | 30-50 | Not Applicable |
| Pumice | 1332-09-8 | 20-40 | Not Applicable |
| Calcium Sodium phosphosilicate (Novamin®) | 65997-18-4 or 359684-27-8 | 12-18 | Not Applicable |
| Sodium Silicate | 1344-09-8 / 215-687-4 | 3-7 | Xi R36/37/38 |
| Titanium Dioxide | 13463-67-7 | 2-6 | Not Applicable |
| Sodium Fluoride | 7681-49-4 / 231-667-8 | 1-5 | T R25, R32, R36/38 |
| Crystalline Silica (Quartz) | 14808-60-7 / 238-878-4 | <1% | Xn R48/20 |

See Section 15 for further information on EU Classification.

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 or discomfort develops or persists.

Skin Contact: Wash skin with plenty of soap and water. Remove contaminated clothing and shoes. Get medical attention if irritation develops. Launder clothing before re-use.

Ingestion: Do not induce vomiting. If conscious, rinse mouth out and give copious amount of milk, or water if milk is not available, to dilute. Never give anything by mouth to an unconscious or convulsing person. 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 PROCEDURES

Extinguishing Media: Use media appropriate for surrounding fire. Cool fire exposed containers and structures with water.

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

Unusual Fire/Explosion Hazards: None known.

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

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.

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

Environmental Precautions: None needed.

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 25°C (77°F). Keep out of direct sunlight.

SECTION 8 EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits:

| | |
|----------|---|
| Glycerin | 5 mg/m ³ TWA PEL (respirable fraction) 10 mg/m ³ TWA TLV |
| Pumice | None Established |

| | |
|---|--|
| Calcium Sodium phosphosilicate (Novamin®) | None Established |
| Sodium Silicates | None Established |
| Titanium Dioxide | 15 mg/m ³ TWA PEL (total dust) 10 mg/m ³ TWA TLV 1.5 mg/m ³ (respirable dust) DFG MAK 10 mg/m ³ (inhalable); 4 mg/m ³ (respirable dust) TWA UK WEL |
| 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 |
| Crystalline Silica (Quartz) | 10 mg/m ³ TWA PEL (respirable fraction) % Silica + 2 0.025 mg/m ³ TWA TLV (respirable fraction) 0.1 mg/m ³ TWA UK WEL 0.15 mg/m ³ TWA MAK |

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: None required for normal use. 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.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Abrasive dispersion of pumice in a viscous solution in various colors and flavors.

Boiling Point: Not available

Freezing Point: Not available

Solubility in Water: Slightly soluble

Vapor Pressure (mmHg): Not available

Evaporation Rate: Not available

% Volatile by Volume: <10%

Flammable Limits in Air: LEL: N/A

UEL: N/A

Melting Point: Not available

Specific Gravity: Not available

pH: 9.5-10.5

Vapor Density: Not available

Viscosity: Not applicable

Flashpoint: Not applicable

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 acids.

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

Contact with acids may form hydrogen fluoride.

Hazardous Polymerization: Will not occur.

SECTION 11 TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Direct contact may cause irritation with redness and tearing. Injury may occur from mechanical irritation.

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, weakness, tremor, spasm or convulsion. The following adverse reactions are possible in individual hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

Chronic Health Effects: Repeated excessive levels of glycerin have been shown to cause kidney, liver and gastrointestinal effects in studies with laboratory animals. Prolonged overexposure to sodium fluoride may cause cardiac disorders and cause damage to the kidney and brain. This product contains a trace amount of crystalline silica. Repeated inhalation of respirable crystalline silica dust may cause a progressive, disabling and sometimes fatal lung disease called silicosis. The crystalline silica in this product is encapsulated in a viscous liquid. Under normal conditions of use, exposure is not expected to occur.

Carcinogenicity: Crystalline silica quartz is listed as "Carcinogenic to Humans" (Group 1) by IARC and "Known to be a Human Carcinogen" by NTP. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP or the EU directive.

Mutagenicity: No data available.

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

Toxicological Data:

| | |
|---|--|
| Glycerin: | Oral Rat LD50: 17,000-27,200 mg/kg Skin Rabbit LD50: >10,000 mg/kg Inhalation rat LC50: >4 mg/L/6hrs |
| Pumice: | No data available |
| Calcium Sodium phosphosilicate (Novamin [®]): | No data available |
| Sodium Silicate: | Oral Rabbit LD50: 12,600 mg/kg Inhalation Rat LC50: >570 mg/m ³ /1 hour Skin Rabbit LD50: >10 gm/kg |
| Titanium Dioxide: | No data available |
| Sodium Fluoride: | Oral Rat LD50: 18 mg/kg |
| Crystalline Silica Quartz: | Oral Rat LD50: >22,500 mg/kg. |

SECTION 12 ECOLOGICAL INFORMATION

| | |
|---|--|
| Glycerin: | 96 hr LC50 fathead minnow: 44,000 mg/L 96 hr LC50 goldfish: >5,000 mg/L |
| Pumice: | No data available |
| Calcium Sodium phosphosilicate (Novamin [®]): | No data available |
| Sodium Silicate: | No data available |
| Titanium Dioxide: | No data available |
| Sodium Fluoride: | LC50/96-hour fish: >100 mg/kg |
| Crystalline Silica Quartz: | 72 hr LC50 carp: >10,000 mg/L |

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

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

U.S. FEDERAL REGULATIONS:

CERCLA 103 Reportable Quantity: Not regulated under CERCLA. Many states have more stringent release reporting requirements. Report spills required under federal, state and local 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

Section 302 Extremely Hazardous Substances (TPQ): None

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

U.S. STATE REGULATIONS

California Proposition 65: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: Crystalline Silica (Quartz): <1%

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.

European Community Labeling: None required

European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

| |
|-------------------------------------|
| SECTION 16 OTHER INFORMATION |
|-------------------------------------|

HMIS Hazard Rating:

Health – 0* Fire Hazard – 0 Reactivity – 0
* chronic health effect

Revision Date: 07/21/2010

Supersedes: Revision date 08/22/2008

DENTSPLY International

DENTSPLY PROFESSIONAL

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC)
1907/2006, Regulation (EC) 1272/2008 and Regulation
(EC) 453/2010)

Date Issued: 21 July 2010
Document Number: 801363
Date Revised: 04 February 2014
Revision Number: 3

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):

NUPRO® Sensodyne® Prophylaxis Paste with
Novamin®, with and without Fluoride

Part/Item Number:

801510, 801511, 801512, 801513, 801514, 801515, 801516,
801517, 801518, 801519, 801520, 801521, 801522, 801523,
801524, 801525, 801528, 801529, 801530, 801531, 801534,
801535, 801536, 801537, 801540, 801541, 965664, 965665,
965666, 965667

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:

For cleaning and polishing procedures as part of a
professionally administered dental prophylaxis
treatment.

Restrictions on Use:

For Professional Use Only. Do not use on persons
hypersensitive to fluoride or other formula ingredients.

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:

DENTSPLY Professional

Manufacturer/Supplier Address:

1301 Smile Way
York, PA 17404

Manufacturer/Supplier Telephone Number:

800-989-8826 or 717-767-8502 (Product Information)

Email address:

ProfessionalMSDS@dentsply.com

1.4 Emergency Telephone Number:

Transportation Emergency Contact Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

| GHS Classification: | | |
|--|---------------|---------------|
| Health | Environmental | Physical |
| Acute Oral Toxicity Category 4 (H302) Eye Irritant Category 2 (H319) Skin Irritant Category 2 (H315) | Not Hazardous | Not Hazardous |

EU Classification: Not classified.

2.2 Label Elements:

Signal Word: Warning



| Hazard Phrases | Precautionary Phrases |
|---|---|
| H302 Harmful if swallowed. H315 Causes skin irritation. H319 Causes serious eye irritation. | P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves, protective clothing, eye protections and face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P332+P313 If skin irritation occurs: Get medical attention. P362 Take off contaminated clothing and wash before reuse. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P330 Rinse mouth. P501 Dispose of contents and container in accordance with local and national regulations. |

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

| Hazardous Components | C.A.S. # | EINECS # | Classification | WT % |
|---|---------------------------|-------------------------|---|-------|
| Glycerin | 56-81-5 | 200-289-5 | Not Applicable | 30-50 |
| Pumice | 1332-09-8 | Not listed | Not Applicable | 20-40 |
| Calcium Sodium Phosphosilicate (Novamin®) | 65997-18-4 or 359684-27-8 | 266-047-6 or Not listed | Not Applicable | 12-18 |
| Sodium Silicate | 1344-09-8 | 215-687-4 | Xi R36/37/38 Eye Irrit. Cat 2A, H319 Skin Irrit. Cat 2, H315 STOT SE Cat 3, H335 | 3-7 |
| Titanium Dioxide | 13463-67-7 | 236-675-5 | Carc. Cat 2, H351 | 2-6 |
| Sodium Fluoride* | 7681-49-4 | 231-667-8 | T, Xi R25, R32, R36/38 Acute Tox. Cat 3, H301 Eye Irrit. Cat 2, H319 Skin Irrit. Cat 2, H315 EUH032 | 1-5 |
| Crystalline Silica (Quartz) | 14808-60-7 | 238-878-4 | Xn 48/20 STOT RE Cat 1, H372 Carc. Cat 1, H350 | <1% |

*Only used in Prophy Paste with Fluoride.

Note: The Titanium Dioxide and Crystalline Silica in this product are not unbound or respirable. Therefore, no warning is required.

The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

| | |
|-------------------|---|
| Eye | Immediately flush eyes with plenty of water for at least 15 minutes while holding the eyelids apart. Remove contact lenses, if present and easy to do. Get medical attention if irritation or discomfort develops or persists. |
| Skin | Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation occurs. Launder clothing before re-use. |
| Inhalation | Remove victim to fresh air. Give artificial respiration if needed. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if symptoms of exposure persist. |
| Ingestion | Do not induce vomiting. If conscious, rinse mouth out and give copious amount of milk, or water if milk is not available, to dilute. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell. |

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Direct contact may cause eye and skin irritation. Harmful if swallowed. Prolonged inhalation of dusts from dried product may cause lung damage. Contains crystalline silica. Prolonged overexposure to respirable crystalline silica may cause lung disease (silicosis) and increase the risk of lung cancer. Risk of cancer depends on duration and level of exposure. The crystalline silica in this product is encapsulated in a viscous liquid. Under normal conditions of use, exposure is not expected to occur.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention should not be required.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.





5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use media appropriate for surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:

Decomposition may release carbon monoxide, carbon dioxide, and acrolein.

5.3 Advice for Fire-Fighters:



| | | | |
|---|---|--|---|
| Fire Fighting Procedures: | Use water to cool fire-exposed containers. Fight fire from safe distance or protected location. | | |
| Precautions for Fire Fighters: | Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. | | |
| Recommended Protective Equipment for Fire Fighters: | | | |
| EYES/FACE | HANDS | RESPIRATORY | THERMAL |
|  |  |  |  |

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing.

Recommended Personal Protective Equipment for Containment and Clean-up:

| EYES/FACE | HANDS | RESPIRATORY | SKIN |
|---|---|-------------|------|
|  |  | | |

6.2 Environmental Precautions:

Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Report releases as required by local, state and federal authorities.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment. 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 SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from heat, direct sunlight and incompatible materials. Do not store above 25°C (77°F).

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| | | |
|---|----------------|---|
| 8.1 Control Parameters: | | |
| Occupational Exposure Limits: | | |
| Glycerin | United States | 5 mg/m ³ (Respirable fraction), 15 mg/m ³ (Total Dust) TWA OSHA PEL (As mist) |
| | Germany | 50 mg/m ³ TWA (Inhalable), 100 mg/m ³ STEL DFG MAK |
| | United Kingdom | 10 mg/m ³ TWA UK WEL |
| | European Union | Belgium: 10 mg/m ³ TWA |
| Pumice | United States | None Established |
| | Germany | None Established |
| | United Kingdom | None Established |
| | European Union | None Established |
| Calcium Sodium Phosphosilicate | United States | None Established |
| | Germany | None Established |
| | United Kingdom | None Established |
| | European Union | None Established |
| Sodium Silicate | United States | None Established |
| | Germany | None Established |
| | United Kingdom | None Established |
| | European Union | None Established |
| Titanium Dioxide | United States | 10 mg/m ³ TWA ACGIH TLV 15 mg/m ³ (Total Dust) TWA OSHA PEL |
| | Germany | None Established |
| | United Kingdom | 10 mg/m ³ (Inhalable), 4 mg/m ³ (Respirable) TWA UK OEL |
| | European Union | Belgium: 10 mg/m ³ TWA |
| Sodium Fluoride* (As Flouride, F) | United States | 2.5 mg/m ³ TWA ACGIH TLV 2.5 mg/m ³ TWA OSHA PEL |
| | Germany | 1 mg/m ³ (Inhalable) TWA, 4 mg/m ³ STEL DFG MAK Skin |
| | United Kingdom | 2.5 mg/m ³ TWA UK OEL |
| | European Union | 2.5 mg/m ³ TWA EU OEL |
| Crystalline Silica as Quartz | United States | $\frac{10 \text{ mg/m}^3}{\% \text{ SiO}_2 + 2}$ TWA OSHA PEL (Respirable fraction) $\frac{30 \text{ mg/m}^3}{\% \text{ SiO}_2 + 2}$ TWA OSHA PEL (Total dust) 0.025 mg/m ³ TWA ACGIH TLV (Respirable) |
| | Germany | None Established |
| | United Kingdom | 0.1 mg/m ³ TWA UK WEL (as Silica, respirable crystalline) |
| | European Union | Belgium: 0.1 mg/m ³ TWA |
| Biological Exposure Limits: | | |
| Sodium Fluoride (as fluorides): Fluoride in urine, Prior to shift, 2 mg/L. Fluoride in urine, End of shift, 3 mg/L. | | |

*Only used in Prophy Paste with Fluoride

8.2 Exposure Controls:

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

Individual Protection Measures (PPE):



Specific Eye/face Protection: None required for normal use. Chemical safety goggles are recommended for bulk handling.

Specific Skin Protection: None required for normal use. Wear impervious gloves such as natural rubber gloves for bulk handling. Impervious clothing as needed to avoid contamination of personal clothing for bulk handling.

Specific 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.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment

| EYES/FACE | HANDS | RESPIRATORY | SKIN |
|---|---|-------------|------|
|  |  | | |

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

| | | | |
|---|---|--|--|
| Appearance: | Abrasive dispersion of pumice in a viscous solution in various colors and flavors | Explosive limits: | LEL: Not applicable UEL: Not applicable |
| Odor: | Characteristic | Vapor pressure (mmHg): | Not determined |
| Odor threshold: | Not determined | Vapor density: | Not determined |
| pH: | 9.5-10.5 | Relative density: | Not determined |
| Melting/freezing point: | Not determined | Solubility(ies): | Slightly soluble in water. |
| Initial boiling point and boiling range: | Not determined | Partition coefficient: n-octanol/water: | Not determined |
| Flash point: | Not applicable | Auto-ignition temperature: | Not applicable |
| Evaporation rate: | Not determined | Decomposition temperature: | Not determined |
| Flammability (solid, gas): | Not applicable | Viscosity: | Not determined |
| Explosive Properties: | Not explosive | Oxidizing Properties: | Not an oxidizer |

9.2 Other Information: % Volatile by Volume: <10%

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal storage and handling conditions.

10.3 Possibility of Hazardous Reactions: Hazardous polymerization will not occur. Contact with acids liberated very toxic gases. Contact with acids may form hydrogen fluoride. Crystalline silica will dissolve in hydrofluoric acid and produce silicone tetrafluoride.

10.4 Conditions to Avoid: Avoid excessive heat and direct sunlight.

10.5 Incompatible materials: Avoid oxidizing agents and acids.

10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide, carbon dioxide, and acrolein.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Direct contact may cause irritation with redness and tearing. Injury may occur from mechanical irritation.

Skin: May cause skin irritation.

Ingestion: May cause salivation, nausea, vomiting. Ingestion of large quantities may cause abdominal pain, weakness, tremor, spasm or convulsion. The following adverse reactions are possible in individuals hypersensitive to fluoride*: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

Inhalation: No adverse effects are expected under normal use conditions.

Chronic Health Effects: Repeated excessive exposures to glycerin may cause increased fat levels in the blood and damage to the kidney and liver. Prolonged overexposure to sodium fluoride* may cause cardiac disorders, damage to the kidney and brain, and fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel. Excessive inhalation of respirable crystalline silica may cause a progressive, disabling and sometimes fatal lung disease called silicosis. The crystalline silica in this product is encapsulated in a viscous liquid and under normal conditions of use; no exposure is expected to occur.

(*Only pertains to Prophy Paste with Fluoride)

Irritation: Sodium Silicate: Corrosive to not irritating in rabbit skin. Highly irritating to not irritating in rabbit eyes. Sodium Fluoride: Highly irritating to not irritating in rabbit skin. Highly irritating to moderately irritating to rabbit eyes.

Corrosivity: This product is not a corrosive material.

Sensitisation: No data available. This product is not expected to cause sensitization.

Carcinogenicity: Glycerin: No increase in tumor incidence was found in a 2 year oral feeding study with rats at doses of 5 and 10 g/kg. Sodium Fluoride: 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. Titanium Dioxide: This product contains titanium dioxide, which is listed by IARC as a suspected carcinogen (Group 2B). Titanium dioxide only presents a risk of cancer by inhalation of very fine dust. In this product, the titanium dioxide is incorporated into a viscous liquid and is not present as a respirable dust. There is no exposure to respirable titanium dioxide dust in the normal use of this product. Crystalline silica is classified as a Group 1 carcinogen by IARC, and "Known to be a Human Carcinogen" by NTP. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

Mutagenicity: Glycerin: Negative in AMES, in-vitro sister chromatid exchange and unscheduled DNA synthesis. Sodium fluoride was negative in the AMES test but was positive 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.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing eye or skin disease may be at increased risk from exposure.

Acute Toxicity Data:

Glycerin: Glycerin: Oral rabbit LD50- >12,600 mg/kg ; Skin rabbit LD50 - >10,000 mg/kg; Inhalation rat LC50 - >570 mg/m³/1 hr

Pumice: No toxicity data available

Calcium Sodium Phosphosilicate: No toxicity data available

Sodium Silicate: Oral rat LC50 – 1960 mg/kg; Skin rabbit LD50 - >4640 mg/kg

Titanium dioxide: Oral rat LD50 - >20000 mg/kg; Skin hamster LD50 ->10000 mg/kg

Sodium Fluoride: Oral Rat LD50- 32 mg/kg

Crystalline Silica: Oral rat LD50 - >22,500 mg/kg

Reproductive Toxicity Data: 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. 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.

Specific Target Organ Toxicity (STOT):

Single Exposure: Glycerin: When place into the eye of a rabbit, glycerin will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells. 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.

Repeated Exposure: Glycerin: 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. Sodium Fluoride: Brain, liver, kidneys 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. Crystalline Silica: Repeated inhalation of crystalline silica may cause lung damage and silicosis.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Glycerin: 24 hr LC50 Goldfish - >5000 mg/L; 48 hr EC50 Daphnia magna -10,000 mg/L

Sodium Silicate: 96 hr LC50 Zebra fish – 3185 mg/L; 96 hr EC50 Daphnia magna – 216 mg/L

Sodium Fluoride*: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) - 83.7 mg/L, 48 hr EC50 Daphnia magna - 98 mg/L

Crystalline Silica Quartz: 72 hr LC50 Carp - >10,000 mg/L.

12.2 Persistence and Degradability: Glycerin is readily biodegradable (96% in 24 hours). Biodegradability does not apply to inorganic compounds.

12.3 Bio-accumulative Potential: Glycerin is not expected to bioconcentrate in fish and aquatic organisms.

12.4 Mobility in Soil: Glycerin: Very high mobility in soil.

12.5 Results of PBT and vPvB Assessment: Not applicable.

12.6 Other Adverse Effects: No adverse effects are expected.

*Only in Propyl Paste with Fluoride

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

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

Properties (Physical/Chemical) Affecting Disposal: Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

| | 14.1 UN Number | 14.2 UN Proper Shipping Name | 14.3 Hazard Class(s) | 14.4 Packing Group | 14.5 Environmental Hazards |
|-----------|----------------|------------------------------|----------------------|--------------------|----------------------------|
| DOT | None | Not Regulated | None | None | Not applicable |
| ADR/RID | None | Not Regulated | None | None | Not applicable |
| IMDG | None | Not Regulated | None | None | Not applicable |
| IATA/ICAO | None | Not Regulated | None | None | Not applicable |

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 20,000 lbs (based on the RQ of 1,000 lbs for Sodium Fluoride present at 1-5%). Report spills required under federal, state and local regulations.

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

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

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: | Yes | 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 substances known to the state of California to cause cancer and/or reproductive toxicity:

| Components | C.A.S. # | WT % |
|------------------------------|------------|------|
| Titanium Dioxide | 13463-67-7 | 2-6 |
| Crystalline Silica as Quartz | 14808-60-7 | <1% |

Note: The Titanium Dioxide and Crystalline Silica in this product are not unbound or respirable. Therefore, no warning is required.

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: All components requiring registration have been pre-registered.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2* Flammability – 0 Physical Hazard – 0

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

Xn Harmful

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation

Carc Cat 1 Carcinogen Category 1

Carc Cat 2 Carcinogen Category 2

H350 May cause cancer

H351 Suspected of causing cancer

Supersedes: 25 May 2011

Date Revised: 04 February 2014

Revision Summary: Converted MSDS to Reach SDS. Updated all sections. Revised Part/Item Numbers in section 1.1.

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

DENTSPLY International

DENTSPLY PROFESSIONAL

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 25 July 2008
Document Number: 801360
Date Revised: 25 September 2014
Revision Number: 3

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):

NUPRO® Prophylaxis Paste with and without Fluoride

Part/Item Numbers:

638027, 638028, 801111, 801112, 801122, 801126, 801127, 801171, 801211, 801212, 801213, 801221, 801222, 801223, 801225, 801226, 801227, 801231, 801232, 801235, 801299, 801300, 801301, 801302, 801306, 801307, 801308, 801309, 801310, 801311, 801312, 801313, 801314, 801317, 801318, 801319, 801321, 801322, 801326, 801327, 801328, 801329, 801330, 801331, 801332, 801333, 801334, 801335, 801336

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:

For cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment.

Restrictions on Use:

For Professional Use Only. Do not use on persons hypersensitive to fluoride or other formula ingredients.

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:

DENTSPLY Professional

Manufacturer/Supplier Address:

1301 Smile Way
York, PA 17404

Manufacturer/Supplier Telephone Number:

800-989-8826 or 717-767-8502 (Product Information)

Email address:

ProfessionalMSDS@dentsply.com

1.4 Emergency Telephone Number:

Transportation Emergency Contact Number:

800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

| GHS Classification: | | |
|----------------------------------|---------------|---------------|
| Health | Environmental | Physical |
| Acute Toxicity Category 4 (H302) | Not Hazardous | Not Hazardous |

EU Classification: Harmful (Xn) R22

2.2 Label Elements:



Signal Word: Warning

Contains Sodium Fluoride

| Hazard Phrases | Precautionary Phrases |
|----------------------------|--|
| H302 Harmful if swallowed. | P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P330 Rinse mouth. P501 Dispose of contents and container in accordance with local and national regulations. |

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

| Hazardous Components | C.A.S. # | EINECS # | Classification | WT % |
|--|------------|------------|---|-------|
| Pumice | 1332-09-8 | Not listed | Not Applicable | 45-55 |
| Glycerin | 56-81-5 | 200-289-5 | Not Applicable | 30-40 |
| Sodium Fluoride | 7681-49-4 | 231-667-8 | T, Xi R25, R32, R36/38 Acute Tox. Cat 3, H301 Eye Irrit. Cat 2, H319 Skin Irrit. Cat 2, H315 EUH032 | 1-<5 |
| Sodium Silicate | 1344-09-8 | 215-687-4 | Xi R36/37/38 Eye Irrit. Cat 2A, H319 Skin Irrit. Cat 2, H315 STOT SE Cat 3, H335 | 1-<5 |
| Diatomaceous Earth, Natural (kieselguhr) | 61790-53-2 | 231-545-4 | Not Applicable | <5 |
| Crystalline Silica (Quartz) | 14808-60-7 | 238-878-4 | Xn 48/20 STOT RE Cat 1, H372 Carc. Cat 1, H350 | <1 |

Note: The Crystalline Silica in this product is not unbound or respirable. Therefore, no warning is required.

The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

| | |
|-------------------|---|
| Eye | Flush victim's eyes with water. Seek medical attention if irritation occurs or persists. |
| Skin | Wash skin with soap and water. Remove and launder clothing before re-use. |
| Inhalation | Remove victim to fresh air. Give artificial respiration if needed. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if symptoms of exposure persist. |
| Ingestion | Do not induce vomiting. If conscious, rinse mouth out and give copious amount of milk, or water if milk is not available, to dilute. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell. |

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Direct contact may cause eye. Prolonged skin contact may cause irritation. Harmful if swallowed. Prolonged inhalation of dusts from dried product may cause lung damage. Prolonged over exposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel. Contains crystalline silica. Prolonged overexposure to respirable crystalline silica may cause lung disease (silicosis) and increase the risk of lung cancer. Risk of cancer depends on duration and level of exposure. The crystalline silica in this product is encapsulated in a viscous liquid. Under normal conditions of use, exposure is not expected to occur.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention should not be required.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.





5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use media appropriate for surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:

Decomposition may release carbon monoxide, carbon dioxide, and acrolein.

5.3 Advice for Fire-Fighters:

| | | | |
|---|---|--|---|
| Fire Fighting Procedures: | Use water to cool fire-exposed containers. Fight fire from safe distance or protected location. | | |
| Precautions for Fire Fighters: | Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. | | |
| Recommended Protective Equipment for Fire Fighters: | | | |
| EYES/FACE | HANDS | RESPIRATORY | THERMAL |
|  |  |  |  |

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with eyes and prolonged skin contact. Do not breathe dust, mist or vapors. Ventilate area. Wear appropriate protective clothing as described in Section 8.

Recommended Personal Protective Equipment for Containment and Clean-up:

| EYES/FACE | HANDS | RESPIRATORY | SKIN |
|-----------|-------|-------------|------|
| | | | |

6.2 Environmental Precautions:

Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Report releases as required by local, state and federal authorities.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes, skin and clothing. Do not breathe dust, mist or vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. 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 SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from heat, direct sunlight and incompatible materials. Do not store above 25°C (77°F).

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

| | | |
|--|----------------|---|
| Pumice | United States | None Established |
| | Germany | None Established |
| | United Kingdom | None Established |
| | European Union | None Established |
| Glycerin | United States | 5 mg/m ³ (Respirable fraction), 15 mg/m ³ (Total Dust) TWA OSHA PEL (As mist) |
| | Germany | 50 mg/m ³ TWA 100 mg/m ³ STEL DFG MAK (Inhalable) |
| | United Kingdom | 10 mg/m ³ TWA UK WEL |
| | European Union | Belgium: 10 mg/m ³ TWA |
| Sodium Fluoride (As Flouride, F) | United States | 2.5 mg/m ³ TWA ACGIH TLV 2.5 mg/m ³ TWA OSHA PEL |
| | Germany | 1 mg/m ³ TWA, 4 mg/m ³ STEL DFG MAK (Inhalable, skin) |
| | United Kingdom | 2.5 mg/m ³ TWA UK OEL |
| | European Union | 2.5 mg/m ³ TWA EU OEL |
| Sodium Silicate | United States | None Established |
| | Germany | None Established |
| | United Kingdom | None Established |
| | European Union | None Established |
| Diatomaceous Earth, Natural (kieselguhr) | United States | 80 mg/m ³ OSHA PEL (total dust) % SiO ₂ |
| | Germany | 4 mg/m ³ TWA DFG MAK (inhalable) |
| | United Kingdom | 1.2 mg/m ³ TWA UK WEL (respirable) |
| | European Union | None Established |
| Crystalline Silica as Quartz | United States | 10 mg/m ³ TWA OSHA PEL (Respirable fraction) % SiO ₂ + 2 30 mg/m ³ TWA OSHA PEL (Total dust) % SiO ₂ + 2 0.025 mg/m ³ TWA ACGIH TLV (Respirable) |
| | Germany | None Established |
| | United Kingdom | 0.1 mg/m ³ TWA UK WEL (as Silica, respirable crystalline) |
| | European Union | Belgium: 0.1 mg/m ³ TWA |

Biological Exposure Limits:

Sodium Fluoride (as fluorides): Fluoride in urine, Prior to shift, 2 mg/L. Fluoride in urine, End of shift, 3 mg/L.

| | | | |
|---|--------------|--------------------|-------------|
| 8.2 Exposure Controls: | | | |
| Appropriate Engineering Controls: No special ventilation normally required. For bulk handling, use with adequate ventilation to maintain exposure levels below the occupational exposure limits. | | | |
| Individual Protection Measures (PPE): Specific Eye/face Protection: Follow facility requirements for operation. Eye glasses are recommended for bulk handling. Specific Skin Protection: None required during the normal use of this product. Wear impervious gloves such as natural rubber if needed to for bulk handling. Specific 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. Specific Thermal Hazards: None required. | | | |
| Recommended Personal Protective Equipment | | | |
| EYES/FACE | HANDS | RESPIRATORY | SKIN |
| | | | |

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

| | | | |
|---|---|--|--|
| Appearance: | Abrasive dispersion of pumice in a viscous solution in various colors and flavors | Explosive limits: | LEL: Not applicable UEL: Not applicable |
| Odor: | Characteristic of flavor | Vapor pressure (mmHg): | Not determined |
| Odor threshold: | Not determined | Vapor density: | Not determined |
| pH: | 9-10 | Relative density: | Not determined |
| Melting/freezing point: | Not determined | Solubility(ies): | Slightly soluble in water. |
| Initial boiling point and boiling range: | Not determined | Partition coefficient: n-octanol/water: | Not determined |
| Flash point: | Not applicable | Auto-ignition temperature: | Not applicable |
| Evaporation rate: | Not determined | Decomposition temperature: | Not determined |
| Flammability (solid, gas): | Not applicable | Viscosity: | Not determined |
| Explosive Properties: | Not explosive | Oxidizing Properties: | Not an oxidizer |

9.2 Other Information: % Volatile by Volume: <10%

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal storage and handling conditions.

10.3 Possibility of Hazardous Reactions: Hazardous polymerization will not occur. Contact with acids liberated very toxic gases. Contact with acids may form hydrogen fluoride. Crystalline silica will dissolve in hydrofluoric acid and produce silicone tetrafluoride.

10.4 Conditions to Avoid: Avoid excessive heat and direct sunlight.

10.5 Incompatible materials: Avoid oxidizing agents and acids.

10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide, carbon dioxide, and acrolein.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Direct contact may cause irritation with redness and tearing. Injury may occur from mechanical irritation.

Skin: Prolonged skin contact may cause irritation.

Ingestion: Harmful if swallowed. May cause salivation, nausea, vomiting. Ingestion of large quantities may cause abdominal pain, weakness, tremor, spasm or convulsion. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

Inhalation: No adverse effects are expected under normal use conditions.

Chronic Health Effects: Repeated excessive exposures to glycerin may cause increased fat levels in the blood and damage to the kidney and liver. Prolonged overexposure to sodium fluoride may cause cardiac disorders, damage to the kidney and brain, and fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel. Excessive inhalation of respirable crystalline silica may cause may cause a progressive, disabling and sometimes fatal lung disease called silicosis. The crystalline silica in this product is encapsulated in a viscous liquid and under normal conditions of use; exposure is not expected to occur.

Irritation: Sodium Silicate: Corrosive to not irritating in rabbit skin. Highly irritating to not irritating in rabbit eyes. Sodium Fluoride: Highly irritating to not irritating in rabbit skin. Highly irritating to moderately irritating to rabbit eyes.

Corrosivity: This product is not a corrosive material.

Sensitization: No data available. This product is not expected to cause sensitization.

Carcinogenicity: Glycerin: No increase in tumor incidence was found in a 2 year oral feeding study with rats at doses of 5 and 10 g/kg. Sodium Fluoride: 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. Crystalline silica is classified as a Group 1 carcinogen by IARC, and "Known to be a Human Carcinogen" by NTP. In this product, the crystalline silica is incorporated into a viscous liquid and is not present as a respirable dust. There is no exposure to respirable crystalline silica dust in the normal use of this product. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Glycerin: Negative in AMES, in-vitro sister chromatid exchange and unscheduled DNA synthesis. Sodium fluoride was negative in the AMES test but was positive 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.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing eye or skin disease may be at increased risk from exposure.

Acute Toxicity Data:

Pumice: No toxicity data available

Glycerin: Oral rabbit LD50- >12,600 mg/kg ; Skin rabbit LD50 - >10,000 mg/kg; Inhalation rat LC50 - >570 mg/m³/1 hr

Sodium Fluoride: Oral Rat LD50- 32 mg/kg

Sodium Silicate: Oral rat LC50 – 1960 mg/kg; Skin rabbit LD50 - >4640 mg/kg

Diatomaceous Earth, Natural: No toxicity data available

Crystalline Silica: Oral rat LD50 - >22,500 mg/kg

Reproductive Toxicity Data: 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. 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.

Specific Target Organ Toxicity (STOT):

Single Exposure: Glycerin: When place into the eye of a rabbit, glycerin will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells. 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.

Repeated Exposure: Glycerin: 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. Sodium Fluoride: Brain, liver, kidneys 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. Crystalline Silica: Repeated inhalation of crystalline silica may cause lung damage and silicosis.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Glycerin: 24 hr LC50 Goldfish - >5000 mg/L; 48 hr EC50 Daphnia magna -10,000 mg/L

Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) - 83.7 mg/L, 48 hr EC50 Daphnia magna - 98 mg/L

Sodium Silicate: 96 hr LC50 Zebra fish – 3185 mg/L; 96 hr EC50 Daphnia magna – 216 mg/L

Crystalline Silica Quartz: 72 hr LC50 Carp - >10,000 mg/L.

12.2 Persistence and Degradability: Glycerin is readily biodegradable (96% in 24 hours). Biodegradability does not apply to inorganic compounds.

12.3 Bio-accumulative Potential: Glycerin is not expected to bioconcentrate in fish and aquatic organisms.

12.4 Mobility in Soil: Glycerin: Very high mobility in soil.

12.5 Results of PBT and vPvB Assessment: Not applicable.

12.6 Other Adverse Effects: No adverse effects are expected.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

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

Properties (Physical/Chemical) Affecting Disposal: Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

| | 14.1 UN Number | 14.2 UN Proper Shipping Name | 14.3 Hazard Class(s) | 14.4 Packing Group | 14.5 Environmental Hazards |
|------------------|----------------|------------------------------|----------------------|--------------------|----------------------------|
| DOT | None | Not Regulated | None | None | Not applicable |
| ADR/RID | None | Not Regulated | None | None | Not applicable |
| IMDG | None | Not Regulated | None | None | Not applicable |
| IATA/ICAO | None | Not Regulated | None | None | Not applicable |

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 20,000 lbs (based on the RQ of 1,000 lbs for Sodium Fluoride present at 1-<5%). Report spills required under federal, state and local regulations.

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

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

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 substances known to the state of California to cause cancer and/or reproductive toxicity:

| Components | C.A.S. # | WT % |
|------------------------------|------------|------|
| Crystalline Silica as Quartz | 14808-60-7 | <1% |

Note: The Crystalline Silica in this product is not unbound or respirable. Therefore, no warning is required.

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 1 Flammability – 0 Physical Hazard – 0

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

T Toxic

Xi Irritant

Xn Harmful

R22 Harmful if swallowed.

R25 Toxic if swallowed

R32 Contact with acids liberates very toxic gas.

R36/37/38 Irritating to eyes, respiratory system, skin.

R36/38 Irritating to eyes and skin.

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation

Acute Tox. Cat 3 Acute Toxicity Category 3

Acute Tox. Cat 4 Acute Toxicity Category 4
Carc Cat 1 Carcinogen Category 1
Eye Irrit. Cat 2A Eye Irritant Category 2A
Skin Irrit. Cat 2 Skin Irritant Category 2
STOT SE Cat 3 Specific Target Organ Toxicity Single Exposure Category 3
STOT RE Cat 1 Specific Target Organ Toxicity Repeated Exposure Category 1
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H350 May cause cancer.
H372 Causes damage to organs through prolonged or repeated exposure.
EUH032 Contact with acids liberates very toxic gas.

Supersedes: December 27, 2011

Date Revised: 25 September 2014

Revision Summary: Converted MSDS to Reach SDS. Updated all sections. Updated part numbers.

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