



Safety Data Sheet

Issuing Date: 30 Sept 2020

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ECR# 27238

| <i>Section 1. Identification</i> | | |
|--|--|-----------------------------|
| Domestic Product Name: | ProDen Rx 0.044% Oral Rinse | Part Number: 2108MTD |
| Export Product Name: | ProDen Rx 0.044% Oral Rinse | |
| Manufacturer: | Massco Dental 1506 N. 2 nd St. Rogers, AR 72756 | Phone: N/A Fax: N/A |
| Chemical Use: A caries preventive treatment rinse | | |

| <i>Section 2. Hazard(s) Identification</i> | | |
|--|--|--|
| Appearance: | Translucent rinse with an odor matching its flavor | Ratings: |
| Classification: | This chemical is not considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200). | Minimal 0 Slight 1 Moderate 2 Severe 3 Extreme 4 |
| Signal Word: | None | |
| Hazard Information: | None | |
| Precautionary Information: | None | |
| Other Hazards: | No applicable information available | |

| <i>Section 3. Composition and Information for Product Ingredients</i> | | | |
|---|-----------|----------|--------------|
| Chemical Name | CAS # | Synonyms | % W/W |
| Glycerin | 56-81-5 | N/A | Trade Secret |
| Stannous Fluoride | 7783-47-3 | N/A | Trade Secret |

| <i>Section 4. First Aid Measures</i> | |
|--------------------------------------|---|
| Exposure Scenario | First Aid Measures |
| Inhalation | Not an expected route of exposure. Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. |
| Ingestion | Rinse mouth. Do NOT induce vomiting. Get medical attention if symptoms occur. Drink 1 ó 2 glasses of water. |
| Skin Contact | Wash skin with soap and water. Get medical attention if irritation develops and/or persists. |
| Eye Contact | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If eye irritation persists: Get medical advice/ attention. |
| General Precautions | No information available. |
| Note to Physician | Treat symptomatically. |

| <i>Section 5. Fire Fighting Measures</i> | |
|--|--|
| Characteristic | Details |
| Flash Point | Not applicable. |
| Extinguishing Media | Use: Carbon dioxide (CO ₂). Water spray. Alcohol-resistant foam. Dry powder. |
| Specific Hazards Arising from the Chemical | Thermal decomposition can lead to release of irritating gases and vapors |
| Hazardous Combustion Products | Carbon monoxide. Hydrogen fluoride. Stannic oxides |
| Unusual Fire/Explosion Hazards | None |
| Special Protective Equipment | As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. |

| <i>Section 6. Accidental Release Measures</i> | |
|---|--|
| Measure | Details |
| Personal Precautionary Measures | Use personal protective equipment as required. Refer to Section 8. |
| Environmental Precautionary Measures | See Section 12 for additional Ecological Information. Prevent further leakage or spillage if safe to do so. Prevent from entering into soil, ditches, sewers, waterways, and/ or groundwater. |
| Cleaning/Absorption Measures | Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see Section 13). Clean contaminated surface thoroughly. |

| <i>Section 7. Handling and Storage</i> | |
|--|--|
| Action | Details |
| Handling | Use according to package label instructions. |
| Storage | Keep containers tightly closed in a dry, cool and well-ventilated place. Store at controlled room temperature, 20 to 25°C. (68-77°F) NOTE: Incompatible Products; Oxidizing agents. Halogens. Hydrogen peroxide Potassium permanganate. Phosphorous oxides. Sulfuric acid. Nitric acid. Strong alkalis. |

| <i>Section 8. Exposure Controls and Personal Protection</i> | |
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| Action | Details |
| Engineering Controls | Showers, Eyewash stations, Ventilation systems |
| Respiratory Protection | In case of insufficient ventilation wear suitable respiratory equipment. |
| Protective Clothing | Butyl rubber or neoprene is acceptable. |
| Eye Protection | If splashes are likely to occur, wear: Goggles. |
| Hygiene Measures | Wash thoroughly after handling. When using, do not eat, drink or smoke. Provide regular cleaning of equipment, work area and clothing. |
| OSHA PEL | Stannous fluoride (7783-47-3) o TWA: 2 mg/m ³ Sn except oxides TWA: 2.5 mg/m ³ F TWA: 2.5 mg/m ³ dust (vacated) TWA: 2 mg/m ³ Sn except oxides (vacated) TWA: 2.5 mg/m ³ |
| ACGIH TLV | Glycerin (56-81-5) - TWA: 10 mg/m ³ mist Stannous fluoride (7783-47-3) o TWA: 2 mg/m ³ Sn except Tin hydride TWA: 2.5 mg/m ³ F |
| NIOSH IDLH | Stannous fluoride (7783-47-3) o IDLH: 100 mg/m ³ Sn TWA: 2 mg/m ³ except Tin oxides Sn |

Section 9. Physical and Chemical Properties of Product

| Characteristic | Details |
|---------------------------------|---|
| Appearance | Translucent rinse with an odor matching its flavor. |
| pH | 2.0 to 3.0 |
| Specific gravity | 1.25 @ 25°C |
| Boiling point/ Boiling Range | No data available |
| Melting point/ Freezing Point | No data available |
| Flash Point | No data available |
| Flammability | Not flammable |
| Flammability & Explosive Limits | No data available |
| Vapor Pressure | No data available |
| Vapor Density | No data available |
| Relative Density | No data available |
| Solubility | No data available |
| Odor Threshold | No data available |
| Evaporation Rate (nBuAc =1) | No data available |
| Partition coefficient | No data available |
| Auto-ignition temperature | No data available |
| Decomposition temperature | No data available |
| Viscosity | 1000 to 10000 cps |

Section 10. Stability and Reactivity of Product

| Characteristic | Details |
|--------------------------------|---|
| Reactivity/ Chemical Stability | Stable under recommended storage conditions |
| Hazardous Polymerization | Hazardous polymerization may occur |
| Conditions to Avoid | Temperatures above 149°C. |
| Incompatible Materials | Oxidizing agents. Halogens. Hydrogen peroxide Potassium permanganate. Phosphorous oxides. Sulfuric acid. Nitric acid. Strong alkalis. |
| Hazardous Decomposition | Acrolein. |

Section 11. Health Hazard Information

| Toxicity Category | Details |
|--------------------------|---|
| Acute Oral Toxicity | 0% of the mixture consists of ingredient(s) of unknown toxicity. |
| Target Organs | No information available |
| Skin Irritation | May cause irritation |
| Eye Irritation | May cause irritation |
| Inhalation | There is no data available for this product |
| Ingestion | There is no data available for this product |
| General Toxicity | Glycerin: LD50 Oral = 12600 mg/kg (Rat), LD50 Dermal = 21900 mg/kg (Rat), LC50 Inhalation = >570 mg/m ³ (Rat) 1h Stannous fluoride: LD50 Oral = 360 mg/kg (Rat) |

| | |
|-----------------------|---|
| Carcinogenicity | Stannous fluoride; IARC: Group 3 ó Not classifiable as to its Carcinogenicity to humans |
| Mutagenicity | No information available |
| Reproductive Toxicity | No information available |
| Teratogenicity | No information available |

| <i>Section 12. Ecological Information</i> | |
|---|---|
| Characteristic | Details |
| Toxicity | Glycerin: LC50 96h: 51-57 mL/L static (Oncorhynchus mykiss) Glycerin: EC50 24 h: >500 mg/L (Daphina magna) |
| Degradability | Readily biodegradable. |
| Persistence | No information available. |
| Bioaccumulation | Glycerin: Log Pow = -1.76 |
| Mobility in Soil | No information available. |

| <i>Section 13. Disposal of Product</i> | |
|--|---|
| Measure | Details |
| Disposal Methods | This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements. |
| Disposal Container | Dispose of in accordance with local regulations. |
| Waste Handling | No applicable information available |

| <i>Section 14. Transport Information</i> | | |
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| Land Transportation | | |
| DOT (non-bulk) | DOT Shipping Name | Not regulated |
| | UN/NA Number | N/A |
| | Hazard Class | N/A |
| | Packing Group | N/A |
| DOT (bulk) | DOT Shipping Name | Not regulated |
| | UN/NA Number | N/A |
| | Hazard Class | N/A |
| | Packing Group | N/A |

| <i>Section 15. Regulatory Information</i> | |
|---|--|
| Category | Details |
| TSCA Inventory | United States Toxic Substances Control Act Section 8(b) Inventory - Complies |
| DSL/NDSL | Canadian Domestic Substances List/Non-Domestic Substances List - Complies |
| SARA Hazard Categories | Acute Health Hazard No Chronic Health Hazard No Fire Hazard No Sudden Release of Pressure Hazard No Reactive Hazard No |
| CERCLA | This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response |

| | |
|--------------------------------------|--|
| | Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material. |
| Clean Water Act | This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42). |
| California Proposition 65 | This product does not contain any Proposition 65 chemicals. |
| U.S. State Right-to-Know Regulations | Glycerin; New Jersey, Massachusetts, Pennsylvania, Rhode Island Stannous fluoride; New Jersey and Rhode Island |

Section 16. Other Information

Preparation and Release Date: 30 Sept 2020 ECR # 27238

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