Safety Data Sheet
Enamelon® Preventive Treatment Gel

1. Identification

Product Identifier: 9007285, 9007295
Trade name: Enamelon® Preventive Treatment Gel
Recommended Use: Dental Product, Dental Preventative
Restriction on Use: Oral Care Use

Details of the Supplier of the Safety Data Sheet:
Manufacturer/Supplier:
Premier Dental Products Company
1710 Romano Drive
Plymouth Meeting, PA 19462
Ph: 610-239-6000
Fx: 610-239-6171
Emergency telephone number: 610-239-6000

*2. Hazard(s) Identification
Classification of the substance or mixture:

⚠️ GHS07
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2B H320 Causes eye irritation.

Label elements:
GHS label elements
The product is classified and labeled according to the Globally Harmonized System (GHS).
Hazard pictograms:

⚠️ GHS07

Signal word: Warning

Hazard-determining components of labeling:
N-LAUCYLSARCOSINE

Hazard statements:
H315+H320 Causes skin and eye irritation.

Precautionary statements:
P264 Wash thoroughly after handling.
P280 Wear protective gloves.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

Unknown acute toxicity:
This value refers to knowledge of known, established toxicological or ecotoxicological values.
12 % of the mixture consists of component(s) of unknown toxicity.
Classification system: NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme
NFPA ratings (scale 0 - 4)

Health = 1
Fire = 1
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = 1
Fire = 1
Physical Hazard = 0

Hazard(s) not otherwise classified (HNOC): None known

3. Composition/Information on Ingredients
   Chemical characterization: Mixtures
   Description: Mixture of substances listed below with non-hazardous additions.

<table>
<thead>
<tr>
<th>CAS #:</th>
<th>Chemical Name</th>
<th>Concentration %:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 25322-68-3</td>
<td>Polyethylene Glycol</td>
<td>15-40%</td>
</tr>
<tr>
<td>CAS: 56-81-5</td>
<td>Glycerol</td>
<td>15-40%</td>
</tr>
<tr>
<td>RTECS: MA 8050000</td>
<td>Precipitated silica gel (Silica-Amorphous)</td>
<td>5-25%</td>
</tr>
<tr>
<td>CAS: 112926-00-8</td>
<td>Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)</td>
<td>Proprietary%</td>
</tr>
<tr>
<td>RTECS: RTECS: VV7</td>
<td>Precipitated silica gel (Silica-Amorphous)</td>
<td>5-25%</td>
</tr>
<tr>
<td>CAS: 7778-18-9</td>
<td>Calcium Sulfate anhydrous</td>
<td>1-5%</td>
</tr>
<tr>
<td>CAS: 61789-40-0</td>
<td>Cocamidopropyl Betaine</td>
<td>1-5%</td>
</tr>
<tr>
<td>CAS: 7558-80-7</td>
<td>Sodium Phosphate, monobasic, anhydrous</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

Additional information:
The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

4. First-Aid Measures
   Description of first aid measures:
   After inhalation:
   Supply fresh air; consult doctor in case of complaints.
   In case of unconsciousness place patient stably in side position for transportation.
   After skin contact:
   Wash with soap and water.
   If skin irritation occurs, consult a doctor.
   After eye contact:
   If easy to do so, remove contact lenses if worn. If eye irritation occurs, consult a doctor.
   After swallowing:
   Do not induce vomiting without medical advice.
   If swallowed and symptoms occur, consult a doctor.
   Information for doctor:
   Most important symptoms and effects, both acute and delayed: No further relevant information available.
   Indication of any immediate medical attention and special treatment needed:
   No further relevant information available.

5. Fire-Fighting Measures
   Extinguishing media:
   Suitable extinguishing agents: Use fire fighting measures that suit the environment.
   Special hazards arising from the substance or mixture: No further relevant information available.
Advice for firefighters:

Protective equipment:
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Not required.

Environmental precautions: Do not allow to enter sewers/surface or ground water.

Methods and material for containment and cleaning up:
Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust). Dispose of the collected material according to regulations.

Reference to other sections:
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

Protective Action Criteria for Chemicals

<table>
<thead>
<tr>
<th>PAC-1:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>25322-68-3</td>
<td>Polyethylene Glycol</td>
<td>30 mg/m³</td>
</tr>
<tr>
<td>56-81-5</td>
<td>Glycerol</td>
<td>45 mg/m³</td>
</tr>
<tr>
<td>112926-00-8</td>
<td>Precipitated silica gel (Silica-Amorphous)</td>
<td>18 mg/m³</td>
</tr>
<tr>
<td>9003-11-6</td>
<td>Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)</td>
<td>6.9 mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PAC-2:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>25322-68-3</td>
<td>Polyethylene Glycol</td>
<td>1,300 mg/m³</td>
</tr>
<tr>
<td>56-81-5</td>
<td>Glycerol</td>
<td>180 mg/m³</td>
</tr>
<tr>
<td>112926-00-8</td>
<td>Precipitated silica gel (Silica-Amorphous)</td>
<td>200 mg/m³</td>
</tr>
<tr>
<td>9003-11-6</td>
<td>Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)</td>
<td>76 mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PAC-3:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>25322-68-3</td>
<td>Polyethylene Glycol</td>
<td>7,700 mg/m³</td>
</tr>
<tr>
<td>56-81-5</td>
<td>Glycerol</td>
<td>1,100 mg/m³</td>
</tr>
<tr>
<td>112926-00-8</td>
<td>Precipitated silica gel (Silica-Amorphous)</td>
<td>1,200 mg/m³</td>
</tr>
<tr>
<td>9003-11-6</td>
<td>Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)</td>
<td>460 mg/m³</td>
</tr>
</tbody>
</table>

7. Handling and Storage

Handling

Precautions for safe handling: No special precautions are necessary if used correctly.

Information about protection against explosions and fires: No special measures required.

Conditions for safe storage, including any incompatibilities:

Storage

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: None.

Specific end use(s): No further relevant information available.

8. Exposure Controls/Personal Protection

Additional information about design of technical systems: No further data; see section 7.

Control parameters:

Components with occupational exposure limits:
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

<table>
<thead>
<tr>
<th>25322-68-3 Polyethylene Glycol</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>WEEL</td>
<td>Long-term value: 10 mg/m³ (H); MW&gt;200</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>56-81-5 Glycerol</th>
<th></th>
<th></th>
</tr>
</thead>
</table>
**PEL** | Long-term value: 15* 5** mg/m³
mist; *total dust **respirable fraction
---|---
**TLV** | TLV withdrawn-insufficient data human occup. exp.

**112926-00-8 Precipitated silica gel (Silica-Amorphous)**

<table>
<thead>
<tr>
<th>PEL</th>
<th>20mppcf or 80mg/m³ /%SiO₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>REL</td>
<td>Long-term value: 6 mg/m³</td>
</tr>
<tr>
<td>TLV</td>
<td>TLV withdrawn</td>
</tr>
</tbody>
</table>

**7778-18-9 Calcium Sulfate anhydrous**

<table>
<thead>
<tr>
<th>PEL</th>
<th>Long-term value: 15* 5** mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>REL</td>
<td>Long-term value: 10* 5** mg/m³</td>
</tr>
<tr>
<td>TLV</td>
<td>Long-term value: 10* mg/m³</td>
</tr>
</tbody>
</table>

*total dust **respirable fraction

*as inhalable fraction

**Additional information:** The lists that were valid during the creation of this SDS were used as basis.

**Exposure controls:**

**Personal protective equipment:**

**General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed. Wash hands before breaks and at the end of work.

**Breathing equipment:** Not required.

**Protection of hands:** No chemical-protective gloves required.

**Material of gloves:**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

**Penetration time of glove material:**

The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

**Eye protection:** Not required.

**9. Physical and Chemical Properties**

**Information on basic physical and chemical properties**

**General Information**

**Appearance:**

- **Form:** Paste
- **Color:** Off white
- **Odor:** Mint
- **Odor threshold:** Not determined.

**pH-value @ 20°C (68 °F):** 4.4-5.5

**Change in condition**

- **Melting point/Melting range:** Not determined.
- **Boiling point/Boiling range:** >110°C (°F)
- **Flash point:** >113°C (°F)

**Flammability (solid, gaseous):** Not applicable.

**Auto igniting:** Product is not self-igniting.

**Ignition temperature:** ≥305 °C (≥581 °F)

**Decomposition temperature:** Not determined.

**Explosion limits:**

- **Lower:** Not determined.
- **Upper:** Not determined.

**Vapor pressure @ 20°C (68 °F):** <0.1 hPa (mm Hg)
Density @ 20°C (68 °F): 1.5 g/cm³ (lbs/gal)
Relative density: Not determined.
Vapor density: Not determined.
Evaporation rate: Not determined.

Solubility in / Miscibility with:
  Water: Fully miscible.

Partition coefficient (n-octanol/water): Not determined.

Viscosity:
  Dynamic: Not determined.
  Kinematic: Not determined.

Solvent content:
  Organic solvents: 15-40 %
  VOC content: 25-30 %

Solids content: 22.1-%71.1 %
Other information: No further relevant information available.

10. Stability and Reactivity
Reactivity: No further relevant information available.
Chemical stability: Stable under normal conditions.
Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
Possibility of hazardous reactions: No dangerous reactions known.
Conditions to avoid: Heat, flame and ignition sources.
Incompatible materials: No further relevant information available.
Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological Information
Information on toxicological effects:
Acute toxicity:

<table>
<thead>
<tr>
<th>LD/LC50 values that are relevant for classification:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>25322-68-3 Polyethylene Glycol</strong></td>
</tr>
<tr>
<td>Oral LD50</td>
</tr>
<tr>
<td>Dermal LD50</td>
</tr>
<tr>
<td>Inhalative LC50/96</td>
</tr>
<tr>
<td><strong>56-81-5 Glycerol</strong></td>
</tr>
<tr>
<td>Oral LD50</td>
</tr>
<tr>
<td>Dermal LD50</td>
</tr>
<tr>
<td>Inhalative LC50/96</td>
</tr>
<tr>
<td><strong>9003-11-6 Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)</strong></td>
</tr>
<tr>
<td>Oral LD50 Oral</td>
</tr>
<tr>
<td>Dermal LD50</td>
</tr>
</tbody>
</table>

Primary irritant effect:
On the skin: No irritating effect.
On the eye: Irritating effect.
Additional toxicological information:

Carcinogenic categories:
IARC (International Agency for Research on Cancer):
None of the ingredients are listed.

NTP (National Toxicology Program):
None of the ingredients are listed.

OSHA-Ca (Occupational Safety & Health Administration):
None of the ingredients are listed.
12. Ecological Information

Toxicity:

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Ecological Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precipitated silica gel (Silica-Amorphous)</td>
<td>&gt;1,000 mg/l (Daphnia)</td>
<td>Aquatic toxicity:</td>
</tr>
<tr>
<td>Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)</td>
<td>&gt;100 mg/l (Daphnia)</td>
<td></td>
</tr>
<tr>
<td>Cocamidopropyl Betaine</td>
<td>1-10 mg/l (Green algae) 6.5 mg/l (Daphnia)</td>
<td>Aquatic toxicity:</td>
</tr>
</tbody>
</table>

Persistence and degradability: No further relevant information available.

Behavior in environmental systems:

Bioaccumulative potential: No further relevant information available.

Mobility in soil: No further relevant information available.

Additional ecological information:

General notes:
Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.

Results of PBT and vPvB assessment:

PBT: Not applicable.
vPvB: Not applicable.

Other adverse effects: No further relevant information available.

13. Disposal Considerations

Waste treatment methods:

Recommendation:
Observe all federal, state and local environmental regulations when disposing of this material.

Uncleaned packagings

Recommendation: Disposal must be made according to official regulations.

14. Transport Information

UN-Number:

DOT, ADR/ADN, ADN, IMDG, IATA Non-Regulated Material

UN proper shipping name:

DOT, ADR/ADN, ADN, IMDG, IATA Non-Regulated Material

Transport hazard class(es):

DOT, ADR/ADN, ADN, IMDG, IATA Non-Regulated Material

Class:

Non-Regulated Material

Packing group:

DOT, ADR/ADN, IMDG, IATA Non-Regulated Material

Environmental hazards:
Not applicable.

Special precautions for user:
Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:
Not applicable.

UN "Model Regulation":
Non-Regulated Material

15. Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture:

SARA (Superfund Amendments and Reauthorization):

Section 355 (extremely hazardous substances):
None of the ingredients are listed.

Section 313 (Specific toxic chemical listings):
None of the ingredients are listed.

TSCA (Toxic Substances Control Act):

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>25322-68-3</td>
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</tbody>
</table>
7778-18-9  Calcium Sulfate anhydrous
61789-40-0  Cocamidopropyl Betaine
7558-80-7  Sodium Phosphate, monobasic, anhydrous
7783-47-3  tin difluoride

California Proposition 65:

Chemicals known to cause cancer:
None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for females:
None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for males:
None of the ingredients are listed.

Chemicals known to cause developmental toxicity:
None of the ingredients are listed.

New Jersey Right-to-Know List:

25322-68-3  Polyethylene Glycol
56-81-5  Glycerol
112926-00-8  Precipitated silica gel (Silica-Amorphous)
7778-18-9  Calcium Sulfate anhydrous

New Jersey Special Hazardous Substance List:
None of the ingredients are listed.

Pennsylvania Right-to-Know List:

25322-68-3  Polyethylene Glycol
56-81-5  Glycerol
7778-18-9  Calcium Sulfate anhydrous

Pennsylvania Special Hazardous Substance List:
None of the ingredients are listed.

Carcinogenic categories:

EPA (Environmental Protection Agency):
None of the ingredients are listed.

TLV (Threshold Limit Value established by ACGIH):
None of the ingredients are listed.

NIOSH-Ca (National Institute for Occupational Safety and Health):
None of the ingredients are listed.

GHS label elements
The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms:

⚠️

GHS07

Signal word: Warning

Hazard-determining components of labeling:
N-LAUROYLSARCOSINE

Hazard statements:
H315+H320 Causes skin and eye irritation.
Precautionary statements:
P264 Wash thoroughly after handling.
P280 Wear protective gloves.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

National regulations:
None of the ingredients are listed.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16. Other Information
Premier’s revision date: 08/28/2017
Revision number: 4

Abbreviations and acronyms:
ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety and Health
OSHA: Occupational Safety & Health Administration
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.
SDS created by MSDS Authoring Services www.msdsauthoring.com +1-877-204-9106

Supplier’s Number: 080317

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0817083 Rev4