

# Safety Data Sheet

## Enamelon<sup>®</sup> Preventive Treatment Gel

### 1. Identification

**Product Identifier:** 9007285, 9007295

**Trade name:** Enamelon<sup>®</sup> 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-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.

#### 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.

Hazardous Components:		
CAS #:	Chemical Name:	Concentration %:
CAS: 25322-68-3	Polyethylene Glycol	15-40%
CAS: 56-81-5 RTECS: MA 8050000	Glycerol	15-40%
CAS: 112926-00-8 RTECS: RTECS: VV7	Precipitated silica gel (Silica-Amorphous)	5-25%
CAS: 9003-11-6	Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)	Proprietary%
CAS: 7778-18-9	Calcium Sulfate anhydrous	1-5%
CAS: 61789-40-0	Cocamidopropyl Betaine	1-5%
CAS: 7558-80-7	Sodium Phosphate, monobasic, anhydrous	<1%

#### 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**

<b>PAC-1:</b>		
25322-68-3	Polyethylene Glycol	30 mg/m <sup>3</sup>
56-81-5	Glycerol	45 mg/m <sup>3</sup>
112926-00-8	Precipitated silica gel (Silica-Amorphous)	18 mg/m <sup>3</sup>
9003-11-6	Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)	6.9 mg/m <sup>3</sup>
<b>PAC-2:</b>		
25322-68-3	Polyethylene Glycol	1,300 mg/m <sup>3</sup>
56-81-5	Glycerol	180 mg/m <sup>3</sup>
112926-00-8	Precipitated silica gel (Silica-Amorphous)	200 mg/m <sup>3</sup>
9003-11-6	Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)	76 mg/m <sup>3</sup>
<b>PAC-3:</b>		
25322-68-3	Polyethylene Glycol	7,700 mg/m <sup>3</sup>
56-81-5	Glycerol	1,100 mg/m <sup>3</sup>
112926-00-8	Precipitated silica gel (Silica-Amorphous)	1,200 mg/m <sup>3</sup>
9003-11-6	Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)	460 mg/m <sup>3</sup>

**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.

<b>25322-68-3 Polyethylene Glycol</b>	
WEEL	Long-term value: 10 mg/m <sup>3</sup> (H); MW>200
<b>56-81-5 Glycerol</b>	

PEL	Long-term value: 15* 5** mg/m <sup>3</sup> mist; *total dust **respirable fraction
TLV	TLV withdrawn-insufficient data human occup. exp.
<b>112926-00-8 Precipitated silica gel (Silica-Amorphous)</b>	
PEL	20mppcf or 80mg/m <sup>3</sup> /%SiO <sub>2</sub>
REL	Long-term value: 6 mg/m <sup>3</sup> See Pocket Guide App. C
TLV	TLV withdrawn
<b>7778-18-9 Calcium Sulfate anhydrous</b>	
PEL	Long-term value: 15* 5** mg/m <sup>3</sup> *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m <sup>3</sup> *total dust **respirable fraction
TLV	Long-term value: 10* mg/m <sup>3</sup> *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.

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

**Decomposition temperature:** Not determined.

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

**Danger of explosion:** Product does not present an explosion hazard.

**Explosion limits:**

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

**Vapor pressure @ 20°C (68 °F):** <0.1 hPa (mm Hg)

<b>Density @ 20°C (68 °F):</b>	1.5 g/cm <sup>3</sup> (lbs/gal)
<b>Relative density:</b>	Not determined.
<b>Vapor density:</b>	Not determined.
<b>Evaporation rate:</b>	Not determined.
<b>Solubility in / Miscibility with:</b>	
<b>Water:</b>	Fully miscible.
<b>Partition coefficient (n-octanol/water):</b>	Not determined.
<b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
<b>Solvent content:</b>	
<b>Organic solvents:</b>	15-40 %
<b>VOC content:</b>	25-30 %
<b>Solids content:</b>	22.1-<71.1 %
<b>Other information:</b>	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:**

**LD/LC50 values that are relevant for classification:**

### 25322-68-3 Polyethylene Glycol

Oral	LD50	>5,000 mg/kg (Rat)
Dermal	LD50	>5,000 mg/kg (Rabbit)
Inhalative	LC50/96	10,000 mg/l (Fish - Poecilia reticulata, 96h)

### 56-81-5 Glycerol

Oral	LD50	12,600 mg/kg (Rat)
Dermal	LD50	>10,000 mg/kg (Rabbit)
Inhalative	LC50/96	>50,000 mg/l (Trout)

### 9003-11-6 Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)

Oral	LD50 Oral	>5,000 ml/kg (Rat) The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.
Dermal	LD50	>2,000 mg/kg (Rabbit)

**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:**

<b>Aquatic toxicity:</b>	
<b>112926-00-8 Precipitated silica gel (Silica-Amorphous)</b>	
EC50	>1,000 mg/l (Daphnia)
<b>9003-11-6 Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)</b>	
EC50	>100 mg/l (Daphnia)
<b>61789-40-0 Cocamidopropyl Betaine</b>	
EC50	1-10 mg/l (Green algae) 6.5 mg/l (Daphnia)

**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**

**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):**

<b>Section 355 (extremely hazardous substances):</b>	
None of the ingredients are listed.	
<b>Section 313 (Specific toxic chemical listings):</b>	
None of the ingredients are listed.	
<b>TSCA (Toxic Substances Control Act):</b>	
25322-68-3	Polyethylene Glycol
56-81-5	Glycerol
9003-11-6	Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)

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.**

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**Supplier's Number: 080317**

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