

Safety Data Sheet

Premier® Enamelon® Fluoride Toothpaste

1. Identification

Product Identifier: 9007280, 9007290, 9007270

Trade name: Premier Enamelon Fluoride Toothpaste

Recommended Use: Dental Product, Dental Preventative

Restrictions 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.

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: 13463-67-7	Titanium Dioxide	1-5%
CAS: 97-78-9	N-LAUROYLSARCOSINE	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.

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.

Rinse opened eye for several minutes under running water.

After swallowing: 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

PAC-1:		
25322-68-3	Polyethylene Glycol	30 mg/m ³
56-81-5	Glycerol	45 mg/m ³
112926-00-8	Precipitated silica gel (Silica-Amorphous)	18 mg/m ³
9003-11-6	Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)	6.9 mg/m ³
13463-67-7	Titanium Dioxide	30 mg/m ³
PAC-2:		
25322-68-3	Polyethylene Glycol	1,300 mg/m ³
56-81-5	Glycerol	180 mg/m ³
112926-00-8	Precipitated silica gel (Silica-Amorphous)	200 mg/m ³
9003-11-6	Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)	76 mg/m ³
13463-67-7	Titanium Dioxide	330 mg/m ³
PAC-3:		
25322-68-3	Polyethylene Glycol	7,700 mg/m ³
56-81-5	Glycerol	1,100 mg/m ³
112926-00-8	Precipitated silica gel (Silica-Amorphous)	1,200 mg/m ³
9003-11-6	Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)	460 mg/m ³
13463-67-7	Titanium Dioxide	2,000 mg/m ³

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.

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

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TLV	TLV withdrawn-insufficient data human occup.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TLV	TLV withdrawn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

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)

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: Not miscible or difficult to mix.
Partition coefficient (n-octanol/water): Not determined.
Viscosity:
Dynamic: Not determined.
Kinematic: Not determined.
Solvent content:
Organic solvents: 15-40 %
VOC content: 0.00 %
Solids content: 23.1-<76.1 %
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: No further relevant information available.
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 hours	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 hours	>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)
13463-67-7 Titanium Dioxide		
Oral	LD50	>10,000 mg/kg (Rat)
Dermal	LD50	>10,000 mg/kg (Rabbit)
Inhalative	LC50/4 h	>6.82 mg/l (Rat)

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):**

(a) Although IARC has classified titanium dioxide as possible carcinogenic to human (2B), their summary concludes: "No significant exposure to titanium dioxide is thought to occur during the use of products which titanium dioxide is bound to other materials, such as in cosmetics or in paints."

(b) OSHA does not regulate Titanium Dioxide as a carcinogen. However, under 29 CFR 1910.1200 the SDS must convey the fact that Titanium Dioxide is a potential carcinogen to rats.

13463-67-7	Titanium Dioxide	2B
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:****Aquatic toxicity:****112926-00-8 Precipitated silica gel (Silica-Amorphous)**

EC50	>1,000 mg/l (Daphnia)
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9003-11-6 Poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)

EC50	>100 mg/l (Daphnia)
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61789-40-0 Cocamidopropyl Betaine

EC50	1-10 mg/l (Green algae) 6.5 mg/l (Daphnia)
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13463-67-7 Titanium Dioxide

EC50	>1,000 mg/l (Water flea)
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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):

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):

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

13463-67-7 Titanium Dioxide

97-78-9 N-LAUROYLSARCOSINE

7558-80-7 Sodium Phosphate, monobasic, anhydrous

7783-47-3 tin difluoride

California Proposition 65:

Chemicals known to cause cancer:

13463-67-7 Titanium Dioxide

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

13463-67-7 Titanium Dioxide

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

13463-67-7 Titanium Dioxide

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):		
13463-67-7	Titanium Dioxide	A4
NIOSH-Ca (National Institute for Occupational Safety and Health):		
13463-67-7	Titanium Dioxide	

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.

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 Corr. 1C: Skin corrosion/irritation – Category 1C
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
Carc. 2: Carcinogenicity – Category 2
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

The information contained herein is based on our present knowledge. However, this information shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Premier Dental Products Company makes no warranties, express or implied with respect to, and assumes no responsibility or liability for, the accuracy or completeness of the information contained herein. Premier Dental Products Company urges persons receiving this information to make their own determination as to the information suitability for their particular application.

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