



PREMIER DENTAL PRODUCTS COMPANY

Safety Data Sheet

Premier® Enamel Pro® Varnish

SECTION 1: Identification

1.1 GHS Product identifier

Product name	Premier® Enamel Pro® Varnish
Brand	Enamel Pro® Varnish

1.2 Product Description:

Enamel Pro® Varnish is a fluoride varnish which has a strong desensitizing action when applied to dental surfaces. Enamel Pro® Varnish may be used on moist teeth and leaves a film of varnish which sets in the mouth and allow visual control and verification.

1.3 Recommended use of the chemical and restrictions on use

For dental professionals use only.

1.4 Manufacturer's/Supplier's details

Name	Premier Dental Products Company
Address	1710 Romano Drive Plymouth Meeting PA 19462 USA
Telephone	610-239-6000
Fax	610-239-6171
email	regulatory@premierdentalco.com

1.5 Emergency phone number

610-239-6000

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

GHS classification in accordance with: OSHA (29 CFR 1910.1200)

- Skin corrosion/irritation, Cat. 2
- Sensitization, skin, Cat. 1
- Eye damage/irritation, Cat. 2A
- Specific target organ toxicity (single exposure), Cat. 3
- Flammable liquids, Cat. 2

Safety Data Sheet

Premier® Enamel Pro® Varnish

2.2 GHS label elements, including precautionary statements

Pictograms



Hazard statement(s)

H225	Highly flammable liquid and vapor
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Precautionary statement(s)

P210	Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P241	Use explosion-proof electrical/ventilating/lighting/.../ equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P264	Wash hands thoroughly after handling.
P280	Wear eye protection/face protection/protective gloves.
P302+P352	IF ON SKIN: Wash with plenty of water.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/.../ if you feel unwell.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P333+P313	If skin irritation or rash 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.
P363	Wash contaminated clothing before reuse.
P370+P378	In case of fire: Use fire extinguisher to extinguish.
P501	Dispose of contents/container in accordance with local and national regulations.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Hazardous components

1. Calcium Sulfate Dihydrate

Safety Data Sheet

Premier® Enamel Pro® Varnish

Concentration	1 - 10 % (weight), Proprietary
CAS no.	10101-41-4
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

2. Dibasic Sodium Phosphate

Concentration	1 - 10 % (weight), Proprietary
CAS no.	7558-79-4
H315	Causes skin irritation
H319	Causes serious eye irritation

3. Ethanol

Concentration	10 - 30 % (weight), Proprietary
CAS no.	64-17-5
H225	Highly flammable liquid and vapor

4. Sodium Fluoride

Concentration	1 - 10 % (weight), Proprietary
CAS no.	7681-49-4
H315	Causes skin irritation
H319	Causes serious eye irritation
H317	May cause an allergic skin reaction
H335	May cause respiratory irritation

5. Synthetic Resin

Concentration	50 - 70 % (weight), Proprietary
CAS no.	68990-02-3
H315	Causes skin irritation
H319	Causes serious eye irritation

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

In case of skin contact	There may be mild irritation at the site of contact. Wash immediately with plenty of soap and water.
In case of eye contact	There may be irritation and redness. Bathe the eye with running water for 15 minutes.

Safety Data Sheet
Premier® Enamel Pro® Varnish

If swallowed

There may be irritation of the throat. Wash out mouth with water.

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Suitable extinguishing media for the surrounding fire should be used. Use water-spray to cool containers.

5.2 Specific hazards arising from the chemical

In combustion, emits toxic fumes.

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Turn leaking blister packs leak-side up to prevent the escape of liquid.

6.2 Environmental precautions

Do not discharge into drains or rivers. Contain the spillage using bunding.

6.3 Methods and materials for containment and cleaning up

Absorb into dry earth or sand. Transfer to a closable, labeled salvage container for disposal by an appropriate method.

Reference to other sections

Refer to section 8 of SDS for personal protection details.

SECTION 7: Handling and storage

7.2 Conditions for safe storage, including any incompatibilities

Store between 20°C (68°F) - 25°C (77°F). Do not store at temperature over 25°C (77°F). Do not freeze. Keep away from heat and ignition sources. Keep out of reach of children. Store away from strong acids and oxidizing materials.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

1. Ethanol (CAS: 64-17-5)

1000 ppm STEL ACGIH

Safety Data Sheet

Premier® Enamel Pro® Varnish

1900 mg/m³ TWA OSHA

2. Sodium Fluoride (CAS: 7681-49-4)

2.5mg/m³ TWA ACGIH

2.5mg/ m³ TWA OSHA

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Safety glasses. Ensure eye bath is at hand.

Skin protection

Protective clothing.

Body protection

Protective clothing. Protective gloves

Respiratory protection

Respiratory protection not required.

SECTION 9: Physical and chemical properties

Appearance, such as physical state and color	White to off white colored liquid
Odor	Not available
Odor threshold	Not available
pH	Not available
Melting point and freezing point	Not available
Initial boiling point and boiling range	Not available
Flash point	Not available
Evaporation rate	Slow
Flammability, in the case of solids and gases	Not available
Upper and lower flammability or explosive limits	Not available
Vapor pressure	Not available
Vapor density	Not available
Relative density	Not available
Solubility	Not available
Partition coefficient — n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available

Additional properties

Physical state	Liquid
Color	Off-white

Safety Data Sheet

Premier® Enamel Pro® Varnish

Particle characteristics

Not available

Further safety characteristics (supplemental)

Also soluble in: Ethanol

SECTION 10: Stability and reactivity

10.2 Chemical stability

Stable under normal conditions for two (2) years after the date of manufacturing.

10.4 Conditions to avoid

Heat

10.5 Incompatible materials

Strong oxidizing agents. Strong acids.

10.6 Hazardous decomposition products

May produce carbon monoxide, carbon dioxide and toxic fumes

SECTION 11: Toxicological information

Information on toxicological effects

Toxicological data not available for the product itself. The data provided are for the ingredients listed below.

Ethanol:

ORL RAT LD₅₀: 7060mg/kg

Sodium Fluoride:

ORL RAT LD₅₀: 52mg/kg

Acrylates Copolymer:

ORL RAT LD₅₀: >2000mg/kg

Refer to section 4 of SDS for routes of exposure and corresponding symptoms.

SECTION 12: Ecological information

ACUTE TOXICITY

Sodium Fluoride: 96 hrs. LC₅₀ rainbow trout: 200 mg/L.

Ethanol: 96 hrs. LC₅₀ rainbow trout: >10,000 mg/L.

Acrylates Copolymer: 96 hrs. LC₅₀ rainbow trout: > 10,000 mg/l

Safety Data Sheet

Premier® Enamel Pro® Varnish

Persistence and degradability

Biodegradable.

Bioaccumulative potential

No bioaccumulation potential.

Mobility in soil

Readily absorbed into soil.

Other adverse effects

Negligible ecotoxicity.

SECTION 13: Disposal considerations

Disposal methods

Other disposal recommendations

The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

SECTION 14: Transport information

DOT (US)

UN Number: UN 1170

Class: 3

Packing Group: II

Proper Shipping Name: Ethanol solutions

Reportable quantity (RQ): n/a

Marine pollutant: n/a

Poison inhalation hazard: n/a

IMDG

UN Number: UN 1170

Class: 3

Packing Group: II

EMS Number: n/a

Proper Shipping Name: Ethanol solutions

IATA

UN Number: UN 1170

Class: 3

Packing Group: II

Proper Shipping Name: Ethanol solutions

SECTION 15: Regulatory information

15.2 Chemical Safety Assessment

Hazard Category for Section 311/312:

Acute Health, Fire Hazard.

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 at or above reportable quantity.

Section 302 extremely hazardous Substances (TPQ):

None at or above reportable quantity.

EPA Toxic Substances Control Act (TSCA) Status:

This product is regulated by the Food and Drug Administration; and not subject to chemical notification requirements.

Risk phrases:

R11 Highly Flammable

R32 Contact with acids liberates very toxic gas

R43 May cause sensitization by skin contact

R36/38: Irritating to eyes and skin

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

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions.

SECTION 16: Other information

Premier's revision date: 04/15/2025

Revision number: 10

DCR No: 040-2025

16.1 Further information/disclaimer

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.