

Safety Data Sheet
according to WHS Regulations

Printing date 21.05.2024

Revision: 14.05.2024

1 Identification

· **Product identifier**

· **Trade name:** Enamelast™

· **Article number:**

SDS 352-001.16R01, 1001036, 1005983, 1006179, 1006557, 1009274, 71122, 12280, 13454, 5784, 5785, 4518, 4363-P3, 4947, 4518-CN, 4518-JP, 4518-P3, 4528, 4362-CN, 4363, 4528-CN, 4528-P3, 5329, 4819, 4822, 4362, 4343, 12550, 13784, 4343-CN, 5787, 4344, 2484, 2485, 2486, 4344-P3, 5787, 5187, 3380, 4352, 4352-CN, 5187-CN, 5154, 5782, 5188, 4353, 4353-P3

· **Relevant identified uses of the substance or mixture and uses advised against**

Professional Dental Fluoride Varnish

· **Application of the substance / the mixture** Professional Dental Fluoride Varnish

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Ultradent Products, Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com

Ultradent Australia Pty Ltd.
Level 22/2 Market Street
Sydney NSW 2000
Australia

Email: info.anz@ultradent.com
Toll Free: 1-800-290929

· **Further information obtainable from:** Customer Service

· **Emergency telephone number:**

CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

· **Classification of the substance or mixture**



flame

Flam. Liq. 3

H226 Flammable liquid and vapour.



Acute Tox. 4

H302 Harmful if swallowed.

Acute Tox. 4

H332 Harmful if inhaled.

Skin Irrit. 2

H315 Causes skin irritation.

Serious eye damage/irritation – Category 2A H319 Causes serious eye irritation.

Skin Sens. 1

H317 May cause an allergic skin reaction.

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- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS02, GHS07
- **Signal word** Warning

- **Hazard-determining components of labelling:**
 Hydrogenated Rosin
 Sodium Fluoride
 Bubble Gum Flavor
 Isopulegol
- **Hazard statements**
 H226 Flammable liquid and vapour.
 H302 Harmful if swallowed.
 H332 Harmful if inhaled.
 H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H317 May cause an allergic skin reaction.
- **Precautionary statements**
 P101 If medical advice is needed, have product container or label at hand.
 P102 Keep out of reach of children.
 P103 Read label before use.
 P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
 P241 Use explosion-proof electrical/ventilating/lighting equipment.
 P303+P361+P353 IF ON SKIN (or hair): Remove/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.
 P403+P235 Store in a well-ventilated place. Keep cool.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

64-17-5	Ethyl Alcohol ⚠ Flam. Liq. 2, H225; ⚠ Serious eye damage/irritation – Category 2A, H319	>20-<40%
65997-06-0	Hydrogenated Rosin ⚠ Skin Sens. 1, H317	10-<30%
7681-49-4	Sodium Fluoride ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	>1-<10%
36653-82-4	1-Hexadecanol ⚠ Serious eye damage/irritation – Category 2A, H319	>1-<10%
	Bubble Gum Flavor ⚠ Flam. Liq. 2, H225; ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	>1-<10%
5949-29-1	Citric Acid Monohydrate ⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	>1-<10%

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	Amaretto Flavor	>1-<10%
	⚠ Skin Irrit. 2, H315	
89-78-1	Menthol	>1-<5%
	⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	
	Strawberry Flavor	>1-<10%
	⚠ Flam. Liq. 3, H226; ⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	
	Trade Secret	>1-<5%
	⚠ Skin Corr. 1A, H314	
89-80-5	Trans-p-Menthan-3-One	<1%
	⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317; Flam. Liq. 4, H227	
491-07-6	D,L-Isomenthone	<1%
	⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317; Flam. Liq. 4, H227	
8008-57-9	Orange Oil	<1%
	⚠ Flam. Liq. 3, H226; ⚠ Asp. Tox. 1, H304; ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317	
89-79-2	Isopulegol	<1%
	⚠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; Flam. Liq. 4, H227	
5989-27-5	(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane	<1%
	⚠ Flam. Liq. 3, H226; ⚠ Asp. Tox. 1, H304; ⚠ Skin Irrit. 2, H315; Skin Sens. 1B, H317	

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

· **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **After inhalation:**

This product is a viscous gel, therefore chance of inhalation is extremely low.

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:**

If swallowed in large quantities seek medical attention.

Call for a doctor immediately.

· **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

· **Suitable extinguishing agents:**

CO₂ powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **For safety reasons unsuitable extinguishing agents:** Water with full jet

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- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** Mouth respiratory protective device.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **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 (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **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:**
See product labelling.
Keep container tightly sealed.
- **Specific end use(s)** Professional Dental Fluoride Varnish

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

- **Ingredients with limit values that require monitoring at the workplace:**

64-17-5 Ethyl Alcohol

WES	Long-term value: 1880 mg/m ³ , 1000 ppm
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- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of 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 can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and Chemical Properties

· General Information

· Appearance:

· Form:

Viscous Liquid

· Colour:

White to somewhat yellow

· Odour:

Flavor Dependent

· Odour threshold:

Not determined.

· pH-value:

Not applicable (non-aqueous)

· Change in condition

· Melting point/freezing point:

Undetermined.

· Initial boiling point and boiling range:

Undetermined.

· Flash point:

23 °C

· Flammability (solid, gas):

Flammable.

· Decomposition temperature:

Not determined.

· Auto-ignition temperature:

Product is not selfigniting.

· Explosive properties:

Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· Explosion limits:

· Lower:

Not determined.

· Upper:

Not determined.

· Vapour pressure:

Not determined.

· Density at 20 °C:

0.96-1.03 g/cm³

· Relative density

Not determined.

· Vapour density

Not determined.

· Evaporation rate

Not determined.

· Solubility in / Miscibility with

· water:

Not miscible or difficult to mix.

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- **Partition coefficient: n-octanol/water:** Not determined.
 - **Viscosity:**
 - **Dynamic:** Not determined.
 - **Kinematic:** Not determined.
- | | |
|----------------------------|--|
| · Other information | No further relevant information available. |
|----------------------------|--|

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **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**
Harmful if swallowed.
Harmful if inhaled.

· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	1,040 mg/kg
Dermal	LD50	3,500 mg/kg

64-17-5 Ethyl Alcohol

Oral	LD50	>2,500 mg/kg (Guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
Inhalative	LC50 Fish	>10,000 mg/l (Fish)
	LC50/4 h	39 mg/l (mouse) 20,000 mg/l (rat)

65997-06-0 Hydrogenated Rosin

Oral	LD50	>2,500 mg/kg (Guinea pig)
		>3,000 mg/kg (mouse)
		>4,000 mg/kg (rat)
Dermal	LD50	>2,500 mg/kg (rabbit)

7681-49-4 Sodium Fluoride

Oral	LD50	52 mg/kg (mouse)
	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)

36653-82-4 1-Hexadecanol

Oral	LD50	3,200 mg/kg (mouse)
		5,000 mg/kg (rat)

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Dermal	LD50	<10,000 mg/kg (Guinea pig) >2,600 mg/kg (rabbit)
5949-29-1 Citric Acid Monohydrate		
Oral	LD50	5,790 mg/kg (mouse)
5989-27-5 (R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane		
Oral	LD50	4,400 mg/kg (rat)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological Information

- **Toxicity**

· Aquatic toxicity:	
64-17-5 Ethyl Alcohol	
Algae Toxicity	1,000 mg/l (Algae)
7681-49-4 Sodium Fluoride	
EC50	272 mg/kg (Algae) 98 mg/kg (daphnia)
Algae Toxicity (static)	7 mg/l (Algae)
36653-82-4 1-Hexadecanol	
EC50	676 mg/kg (Algae)

- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it 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**
Dispose of contents/container in accordance with international, federal, state, and local regulations.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

<ul style="list-style-type: none"> · UN-Number · ADG, IMDG, IATA 	UNI986
<ul style="list-style-type: none"> · UN proper shipping name · ADG · IMDG, IATA 	1986 ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol, SODIUM FLUORIDE) ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol, SODIUM FLUORIDE)
<ul style="list-style-type: none"> · Transport hazard class(es) · ADG 	<div style="display: flex; align-items: center; gap: 10px;">   </div> <ul style="list-style-type: none"> · Class · Label
<ul style="list-style-type: none"> · Class · Label 	3 Flammable liquids. 3+6.1
<ul style="list-style-type: none"> · IMDG 	<div style="display: flex; align-items: center; gap: 10px;">   </div> <ul style="list-style-type: none"> · Class · Label
<ul style="list-style-type: none"> · Class · Label 	3 Flammable liquids. 3/6.1
<ul style="list-style-type: none"> · IATA 	<div style="display: flex; align-items: center; gap: 10px;">   </div> <ul style="list-style-type: none"> · Class · Label
<ul style="list-style-type: none"> · Class · Label 	3 Flammable liquids. 3 (6.1)
<ul style="list-style-type: none"> · Packing group · ADG, IMDG, IATA 	II
<ul style="list-style-type: none"> · Environmental hazards: 	Not applicable.
<ul style="list-style-type: none"> · Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category · Stowage Code 	Warning: Flammable liquids. 63 F-E,S-D B SW2 Clear of living quarters.
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code 	Not applicable.

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· **Transport/Additional information:**

· **ADG**

· **Limited quantities (LQ)**

1L

· **Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· **Transport category**

2

· **Tunnel restriction code**

D/E

· **IMDG**

· **Limited quantities (LQ)**

1L

· **Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· **UN "Model Regulation":**

UN 1986 ALCOHOLS, FLAMMABLE, TOXIC, N.O.S.
(ETHYL ALCOHOL, SODIUM FLUORIDE), 3 (6.1), II

15 Regulatory information

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

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **Australian Inventory of Industrial Chemicals**

64-17-5	Ethyl Alcohol
65997-06-0	Hydrogenated Rosin
7681-49-4	Sodium Fluoride
8050-15-5	Hydrogenated Rosin
36653-82-4	1-Hexadecanol
5949-29-1	Citric Acid Monohydrate
89-78-1	Menthol
	Trade Secret
56038-13-2	Sucralose
89-80-5	Trans-p-Menthan-3-One
491-07-6	D,L-Isomenthone
121-32-4	3-ethoxy-4-hydroxybenzaldehyde
121-33-5	Vanillin
8008-57-9	Orange Oil
57-55-6	Propylene Glycol
89-79-2	Isopulegol
494-90-6	4,5,6,7-Tetrahydro-3,6-Dimethylbenzofuran
2623-23-6	l-Menthyl Acetate (1Alpha,2Beta,5Alpha)
5989-27-5	(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane
852379-28-3	N-(4-CyanoMethylPhenyl)-2-Isopropyl-5-Methyl HexaneCarboxamide
9005-65-6	Sorbitan Monooleate, Ethoxylated

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513-86-0	Acetoin
87-99-0	Xylitol
· Standard for the Uniform Scheduling of Medicines and Poisons	
None of the ingredients is listed.	
· Australia: Priority Existing Chemicals	
5989-27-5	(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category P5c** FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **Chemical safety assessment:**
Device is biocompatible when used as directed by dental professionals per ISO 10993-1

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases from Section 3**

- H225 Highly flammable liquid and vapour.
- H226 Flammable liquid and vapour.
- H227 Combustible liquid.
- H301 Toxic if swallowed.
- H304 May be fatal if swallowed and enters airways.
- H310 Fatal in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- 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)
- 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
- Flam. Liq. 2: Flammable liquids – Category 2
- Flam. Liq. 3: Flammable liquids – Category 3
- Flam. Liq. 4: Flammable liquids – Category 4
- Acute Tox. 3: Acute toxicity – Category 3
- Acute Tox. 4: Acute toxicity – Category 4
- Acute Tox. 2: Acute toxicity – Category 2
- Skin Corr. 1A: Skin corrosion/irritation – Category 1A
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
- Skin Sens. 1: Skin sensitisation – Category 1

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Skin Sens. 1B: Skin sensitisation – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Asp. Tox. 1: Aspiration hazard – Category 1
· *** Data compared to the previous version altered.**

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