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*
1 Identification

· **Other means of identification**

· **Trade name: Enamelast™**

· **Article number:**
SDS 352-001.18R01, 71122, 1009274, 1001036, 1005983, 1006179, 1006557, 1005220, 1006161, 4343, 4343-CA, 4343-CN, 4344, 4344-P3, 6910, 15227, 4362, 4363, 4362-CA, 4362-CN, 4363-P3, 6911, 4819, 4822, 6912, 4352, 4352-CA, 4352-CN, 4353, 4353-P3, 5187, 6913, 5187-CA, 5187-CN, 5188, 12280, 13454, 15228, 4518, 4518-CA, 4518-CN, 4518-JP, 4518-P3, 4528, 4528-CA, 4528-CN, 4528-P3, 6909, 4518-1, 4521, 4521-JP, 4521-P3, 4523, 4523-CA, 4523-CN, 4523-P3, S4519, 6895, 6897, 6907, 6896, 6898, 6906

· **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
(800) 552-5512

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) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

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2 Hazard(s) Identification

· **Classification of the substance or mixture**

flame

Flammable liquids – Category 3 H226 Flammable liquid and vapour.

health hazard

Carcinogenicity – Category 1A H350 May cause cancer.

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Acute toxicity - oral – Category 4	H302 Harmful if swallowed.
Acute toxicity - inhalation – Category 4	H332 Harmful if inhaled.
Skin corrosion/irritation – Category 2	H315 Causes skin irritation.
Eye damage/irritation – Category 2A	H319 Causes serious eye irritation.
Skin sensitisation – Category 1	H317 May cause an allergic skin reaction.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** GHS02, GHS07, GHS08
· **Signal word** Danger

· **Hazard-determining components of labelling:**
Hydrogenated Rosin (≥1-<30 %)
Resin acids and Rosin acids, hydrogenated, esters with glycerol (≥0-≤10 %)
Vanilla Flavor (≥0-<5 %)
Sodium Fluoride (>1-<10 %)
Bubble Gum Flavor (≥0-<5 %)
Raspberry Dare Flavor (≥0-<5 %)
· **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.
H350 May cause cancer.
· **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.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

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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 Flammable liquids – Category 2, H225; Eye damage/irritation – Category 2A, H319	≥18-<40%
65997-06-0	Hydrogenated Rosin Skin sensitisation – Category 1, H317	≥1-<30%

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	Resin acids and Rosin acids, hydrogenated, esters with glycerol Acute toxicity - oral – Category 4, H302	≥0-≤10%
7681-49-4	Sodium Fluoride Acute toxicity - oral – Category 3, H301; Acute toxicity - dermal – Category 2, H310; Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319	>1-<10%
36653-82-4	1-Hexadecanol Eye damage/irritation – Category 2A, H319	>1-<10%
	Bubble Gum Flavor Flammable liquids – Category 2, H225; Skin corrosion/irritation – Category 2, H315; Skin sensitisation – Category 1, H317; Specific target organ toxicity (single exposure) – Category 3, H335	≥0-<5%
	Vanilla Flavor Flammable liquids – Category 2, H225; Carcinogenicity – Category 1A, H350	≥0-<5%
5949-29-1	Citric Acid Monohydrate Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335	>0.25-≤3%
	Amaretto Flavor Skin corrosion/irritation – Category 2, H315	≥0-<5%
	Raspberry Dare Flavor Flammable liquids – Category 3, H226; Aspiration hazard – Category 1, H304; Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	≥0-<5%
89-78-1	Menthol Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319	≥0-<5%
	Strawberry Flavor Flammable liquids – Category 3, H226; Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319	≥0-<5%
	Trade Secret Skin corrosion/irritation – Category 1A, H314	>1-<5%
89-80-5	Trans-p-Menthan-3-One Skin corrosion/irritation – Category 2, H315; Skin sensitisation – Category 1, H317; Flammable liquids – Category 4, H227	<1%
491-07-6	D,L-Isomenthone Skin corrosion/irritation – Category 2, H315; Skin sensitisation – Category 1, H317; Flammable liquids – Category 4, H227	<1%
8008-57-9	Orange Oil Flammable liquids – Category 3, H226; Aspiration hazard – Category 1, H304; Skin corrosion/irritation – Category 2, H315; Skin sensitisation – Category 1, H317	<1%
5989-27-5	(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane Flammable liquids – Category 3, H226; Aspiration hazard – Category 1, H304; Skin corrosion/irritation – Category 2, H315; Skin sensitisation – Category 1B, H317	<1%

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

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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:**
CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **For safety reasons unsuitable extinguishing agents:** Water with full jet
· **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 section 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.

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7 Handling and Storage

· **Handling:**
· **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.

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· **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.
· **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

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8 Exposure controls and personal protection

· **Appropriate engineering controls** No further data; see section 7.

· **Ingredients with limit values that require monitoring at the workplace:**	
64-17-5 Ethyl Alcohol	
WES	Long-term value: 1880 mg/m³, 1000 ppm

· **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.
Store protective clothing separately.
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.
· **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

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· **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**	Flammable.
· **Decomposition temperature:**	Not determined.
· **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.
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
· **Dynamic:**	Not determined.
· **Kinematic:**	Not determined.
· **Other information**	
· **Particle characteristics**	Not applicable.
· **Physical state**	Fluid

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.

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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	989-1,040 mg/kg
Dermal	LD50	3,500 mg/kg

64-17-5 Ethyl Alcohol		
Oral	LD50	5,600 mg/kg (guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
	LC50 Fish	>10,000 mg/l (Fish)
Inhalative	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)
Resin acids and Rosin acids, hydrogenated, esters with glycerol		
Oral	LD50	2,000 mg/kg (rat)
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)
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)

· **Primary irritant effect:**
· **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** May cause cancer.
· **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.

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· **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.

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

14 Transport information

· **UN-Number**	
· **ADG, IMDG, IATA**	UN1986
· **UN proper shipping name**	
· **ADG**	1986 ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol, SODIUM FLUORIDE)
· **IMDG, IATA**	ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol, SODIUM FLUORIDE)

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· **Transport hazard class(es)**

· **ADG**

· **Class**	3 Flammable liquids.
· **Label**	3+6.1

· **IMDG**

· **Class**	3 Flammable liquids.
· **Label**	3/6.1

· **IATA**

· **Class**	3 Flammable liquids.
· **Label**	3 (6.1)
· **Packing group**	
· **ADG, IMDG, IATA**	II
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Warning: Flammable liquids.
· **Hazard identification number (Kemler code):**	63
· **EMS Number:**	F-E,S-D
· **Stowage Category**	B
· **Stowage Code**	SW2 Clear of living quarters.
· **Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **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

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· **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
	Resin acids and Rosin acids, hydrogenated, esters with glycerol
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	Polysorbate 80 (Tween 80)
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

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· **National regulations:**

· **Information about limitation of use:**
Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation.
Exceptions can be made by the authorities in certain cases.

· **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.
H302 Harmful 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.
H350 May cause cancer.

· **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
Flammable liquids – Category 2: Flammable liquids – Category 2
Flammable liquids – Category 3: Flammable liquids – Category 3
Flammable liquids – Category 4: Flammable liquids – Category 4
Acute toxicity - oral – Category 3: Acute toxicity – Category 3
Acute toxicity - oral – Category 4: Acute toxicity – Category 4
Acute toxicity - dermal – Category 2: Acute toxicity – Category 2
Skin corrosion/irritation – Category 1A: Skin corrosion/irritation – Category 1A
Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2
Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
Skin sensitisation – Category 1: Skin sensitisation – Category 1
Skin sensitisation – Category 1B: Skin sensitisation – Category 1B
Carcinogenicity – Category 1A: Carcinogenicity – Category 1A
Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3
Aspiration hazard – Category 1: Aspiration hazard – Category 1
· ***** Data compared to the previous version altered.**