Safety data sheet
according to UK REACH

Printing date 22.10.2025 Version number 1 Revision: 22.10.2025

*

1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **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

EC Responsible Person
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Office Phone: +49(0)2203-35-92-0

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

· **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

· **Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**

flame

Flam. Liq. 3 H226 Flammable liquid and vapour.

health hazard

Carc. 1A H350 May cause cancer.

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Acute Tox. 4	H302 Harmful if swallowed.
Acute Tox. 4	H332 Harmful if inhaled.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** GHS02, GHS07, GHS08
· **Signal word** Danger

· **Hazard-determining components of labelling:**
Resin acids and Rosin acids, hydrogenated, esters with glycerol
Vanilla Flavor
Bubble Gum Flavor
Sodium Fluoride
Raspberry Dare Flavor
Trans-p-Menthan-3-One
D,L-Isomenthone
Orange Oil
(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane

· **Hazard statements**

H226	Flammable liquid and vapour.
H302+H332	Harmful if swallowed or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H350	May cause cancer.
H412	Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P103	Read carefully and follow all instructions.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241	Use explosion-proof [electrical/ventilating/lighting] equipment.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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/information on ingredients

· **Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6	Ethyl Alcohol Flam. Liq. 2, H225	≥18-<40%
	Resin acids and Rosin acids, hydrogenated, esters with glycerol Acute Tox. 4, H302	≥0-≤10%
CAS: 7681-49-4 EINECS: 231-667-8	Sodium Fluoride Acute Tox. 3, H301; Acute Tox. 2, H310; Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	>1-<10%
CAS: 8050-15-5 EINECS: 232-476-2	Hydrogenated Rosin Aquatic Chronic 3, H412	≥2.5-<10%
	Bubble Gum Flavor Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≥0-<5%
	Vanilla Flavor Flam. Liq. 2, H225; Carc. 1A, H350	≥0-<5%
CAS: 5949-29-1 EC number: 691-328-9	Citric Acid Monohydrate Skin Irrit. 2, H315	>0.25-≤3%
	Amaretto Flavor Skin Irrit. 2, H315	≥0-<5%
	Raspberry Dare Flavor Flam. Liq. 3, H226; Asp. Tox. 1, H304; Skin Irrit. 2, H315; Skin Sens. 1, H317	≥0-<5%
CAS: 89-78-1 EINECS: 201-939-0	Menthol Skin Irrit. 2, H315; Eye Irrit. 2, H319	≥0-<5%
	Strawberry Flavor Flam. Liq. 3, H226; Skin Irrit. 2, H315; Eye Irrit. 2, H319	≥0-<5%
	Trade Secret Skin Corr. 1A, H314	>1-<5%
CAS: 89-80-5 EINECS: 201-941-1	Trans-p-Menthan-3-One Skin Irrit. 2, H315; Skin Sens. 1, H317	<1%
CAS: 491-07-6 EINECS: 207-727-4	D,L-Isomenthone Skin Irrit. 2, H315; Skin Sens. 1, H317	<1%
CAS: 8008-57-9 EC number: 307-891-8	Orange Oil Flam. Liq. 3, H226; Asp. Tox. 1, H304; Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Skin Sens. 1, H317	<1%
CAS: 5989-27-5 EINECS: 227-813-5	(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane Flam. Liq. 3, H226; Asp. Tox. 1, H304; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315; Skin Sens. 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

· **Description of 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.
· **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 Firefighting measures

· **Extinguishing media**
· **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.
· **Advice for firefighters:**
· **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.
· **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
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

· **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
· **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.

· **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:** Do not store together with acids.
· **Further information about storage conditions:**
See product labelling.
Keep container tightly sealed.
· **Specific end use(s)** Professional Dental Fluoride Varnish

8 Exposure controls/personal protection

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
64-17-5 Ethyl Alcohol	
WEL	Long-term value: 1920 mg/m³, 1000 ppm

· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as 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.
· **Hand protection**

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.

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· **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/face protection**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	Fluid
· **Colour:**	White to somewhat yellow
· **Odour:**	Flavor Dependent
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Flammable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	23 °C
· **Decomposition temperature:**	Not determined.
· **pH**	Not applicable (non-aqueous)
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Not miscible or difficult to mix.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density at 20 °C:**	0.96-1.03 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **Other information**	
· **Appearance:**	
· **Form:**	Viscous Liquid
· **Important information on protection of health and environment, and on safety.**	
· **Ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· **Change in condition**	
· **Evaporation rate**	Not determined.

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void

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· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Flammable liquid and vapour.
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **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 hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Harmful if swallowed or 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)
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)

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	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)
8050-15-5 Hydrogenated Rosin		
Oral	LD50	>5,000 mg/kg (guinea pig) >5,000 mg/kg (rat)
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.
· **Carcinogenicity** May cause cancer.
· **Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

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)
8050-15-5 Hydrogenated Rosin		
Oral	EL50	27 mg/l (daphnia)
	LL50	>1,000 mg/l (Fish)
	72-hour EL50	>1,000 mg/l (Algae)

· **Persistence and degradability** No further relevant information available.
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.
· **Other adverse effects**
· **Remark:** Harmful to fish
· **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.

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Harmful to aquatic organisms

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 or ID number***	
· ***ADR, IMDG, IATA***	*UN1986*
· ***UN proper shipping name***	
· ***ADR***	*1986 ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol, SODIUM FLUORIDE)*
· ***IMDG, IATA***	*ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol, SODIUM FLUORIDE)*
· ***Transport hazard class(es)***	
· ***ADR***	
· ***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***	
· ***ADR, IMDG, IATA***	*II*
· ***Environmental hazards:***	*Not applicable.*
· ***Special precautions for user***	*Warning: Flammable liquids.*

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· **Hazard identification number (Kemler code):**	63
· **EMS Number:**	F-E,S-D
· **Stowage Category**	B
· **Stowage Code**	SW2 Clear of living quarters.
· **Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **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.

· **Poisons Act**

· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

7681-49-4	Sodium Fluoride	Listed

· **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

· **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.

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· **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.
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.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.
EUH032 Contact with acids liberates very toxic gas.

· **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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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
ATE: Acute toxicity estimate values
Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
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
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
Carc. 1A: Carcinogenicity – Category 1A
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
· *** Data compared to the previous version altered.**