

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/14/2024

Reviewed on 05/14/2024

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

· **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

· **Information department:** 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**



GHS02 Flame

Flammable Liquids 3 H226 Flammable liquid and vapor.



GHS07

Acute Toxicity - Oral 4 H302 Harmful if swallowed.
Acute Toxicity - Inhalation 4 H332 Harmful if inhaled.
Skin Irritation 2 H315 Causes skin irritation.
Eye Irritation 2A H319 Causes serious eye irritation.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements** Void

· **Hazard pictograms** GHS02, GHS07

· **Signal word** Warning

· **Health Hazard-determining components of labeling:**

Sodium Fluoride
Bubble Gum Flavor
Isopulegol
Trans-p-Menthan-3-One

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*D,L-Isomenthone**Orange Oil***Hazard statements**

- H226 *Flammable liquid and vapor.*
 H302+H332 *Harmful if swallowed or if inhaled.*
 H315 *Causes skin irritation.*
 H319 *Causes serious eye irritation.*
 H317 *May cause an allergic skin reaction.*

Precautionary statements

- P210 *Keep away from heat/sparks/open flames/hot surfaces. - No smoking.*
 P233 *Keep container tightly closed.*
 P240 *Ground/bond container and receiving equipment.*
 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 thoroughly after handling.*
 P270 *Do not eat, drink or smoke when using this product.*
 P271 *Use only outdoors or in a well-ventilated area.*
 P272 *Contaminated work clothing must not be allowed out of the workplace.*
 P280 *Wear protective gloves/protective clothing/eye protection/face protection.*
 P301+P312 *If swallowed: Call a poison center/doctor if you feel unwell.*
 P330 *Rinse mouth.*
 P303+P361+P353 *If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.*
 P304+P340 *IF INHALED: Remove person to fresh air and keep comfortable for breathing.*
 P305+P351+P338 *If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
 P362+P364 *Take off contaminated clothing and wash it before reuse.*
 P333+P313 *If skin irritation or rash occurs: Get medical advice/attention.*
 P321 *Specific treatment (see on this label).*
 P337+P313 *If eye irritation persists: Get medical advice/attention.*
 P363 *Wash contaminated clothing before reuse.*
 P370+P378 *In case of fire: Use CO₂, powder or water spray to extinguish.*
 P403+P235 *Store in a well-ventilated place. Keep cool.*
 P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

Classification system:**NFPA ratings (scale 0 - 4)****HMIS-ratings (scale 0 - 4)**

HEALTH	2	Health = 2
FIRE	3	Fire = 3
REACTIVITY	0	Reactivity = 0

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3 Composition/information on ingredients

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

- **Dangerous components:**

64-17-5	Ethyl Alcohol	>20-<40%
7681-49-4	Sodium Fluoride	>1-<10%
36653-82-4	1-Hexadecanol	>1-<10%
	Bubble Gum Flavor	>1-<10%
5949-29-1	Citric Acid Monohydrate	>1-<10%
	Amaretto Flavor	>1-<10%
89-78-1	Menthol	>1-<5%
	Strawberry Flavor	>1-<10%
	Trade Secret	>1-<5%
89-80-5	Trans-p-Menthan-3-One	<1%
491-07-6	D,L-Isomenthone	<1%
8008-57-9	Orange Oil	<1%
89-79-2	Isopulegol	<1%
5989-27-5	(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane	<1%

- **Additional information:**

The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

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.
Immediately call 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.

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂ extinguishing 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**
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 protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **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:**
See product labelling.
Keep receptacle tightly sealed.
- **Specific end use(s)** Professional Dental Fluoride Varnish

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
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.

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64-17-5 Ethyl AlcoholPEL Long-term value: 1900 mg/m³, 1000 ppmREL Long-term value: 1900 mg/m³, 1000 ppmSTEL Short-term value: 1000 mg/m³TLV Short-term value: 1000 ppm
A3TWA Short-term value: 1900 mg/m³**89-78-1 Menthol**WEEL Short-term value: 19.2* mg/m³, 3* ppmLong-term value: 6.4* mg/m³, 1* ppm

*OARS WEEL

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

· **Exposure controls**

· **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.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **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 is based 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

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9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Viscous
Color:	White to somewhat yellow
Odor:	Flavor Dependent
Odor threshold:	Not determined.

- **pH-value:** Not applicable (non-aqueous)

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined

- **Flash point:** 23 °C

- **Flammability (solid, gaseous):** Flammable.

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapor pressure:** Not determined.

- **Density at 20 °C:** 0.96-1.03 g/cm³

- **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

- **Other information** No further relevant information available.

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.

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· **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:**

ATE (Acute Toxicity Estimate)

Oral	LD50	1,014-1,037 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)
Inhalative	LC50 Fish	>10,000 mg/l (Fish)
	LC50/4 h	39 mg/l (mouse) 20,000 mg/l (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)
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5989-27-5 (R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane

Oral	LD50	4,400 mg/kg (rat)
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· **Primary irritant effect:**· **on the skin:** Irritant to skin and mucous membranes.· **on the eye:** Irritating effect.· **Sensitization:** Sensitization possible through skin contact.· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Harmful

Irritant

· **Carcinogenic categories**· **IARC (International Agency for Research on Cancer)**

7681-49-4	Sodium Fluoride	3
5989-27-5	(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane	3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

64-17-5 Ethyl Alcohol

Algae Toxicity	1,000 mg/l (Algae)
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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)
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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:**

Water hazard class 1 (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 packagings:**

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

14 Transport information

· **UN-Number**

· **DOT, IMDG, IATA**

UN1986

· **UN proper shipping name**

· **DOT**

· **IMDG, IATA**

Alcohols, flammable, toxic, n.o.s. (Ethyl Alcohol, Sodium fluoride)
ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol,
SODIUM FLUORIDE)

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· **Transport hazard class(es)**· **DOT**

· **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**
 · **DOT, 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 73/78 and the IBC Code** Not Applicable.

· **Transport/Additional information:**

· **DOT**
 · **Quantity limitations** On passenger aircraft/rail: 1 L
 On cargo aircraft only: 60 L

· **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

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15 Regulatory information

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

No further relevant information available.

· **Sara**

· **Section 355 (extremely hazardous substances):**

Trade Secret

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

64-17-5	Ethyl Alcohol	ACTIVE
7681-49-4	Sodium Fluoride	ACTIVE
36653-82-4	1-Hexadecanol	ACTIVE
89-78-1	Menthol	ACTIVE
	Trade Secret	ACTIVE
89-80-5	Trans-p-Menthan-3-One	ACTIVE
491-07-6	D,L-Isomenthone	ACTIVE
8008-57-9	Orange Oil	ACTIVE
89-79-2	Isopulegol	ACTIVE
5989-27-5	(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

64-17-5 Ethyl Alcohol

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

64-17-5	Ethyl Alcohol	A3
7681-49-4	Sodium Fluoride	A4

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

None of the ingredients is listed.

· **Chemical safety assessment:**

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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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.

- **Department issuing SDS:** Environmental, Health, and Safety
- **Contact:** Customer Service
- **Date of preparation / last revision** 05/14/2024
- **Abbreviations and acronyms:**
 - IMDG: International Maritime Code for Dangerous Goods
 - DOT: US Department of Transportation
 - 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)
 - NFPA: National Fire Protection Association (USA)
 - HMIS: Hazardous Materials Identification System (USA)
 - 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
 - OSHA: Occupational Safety & Health
 - TLV: Threshold Limit Value
 - PEL: Permissible Exposure Limit
 - REL: Recommended Exposure Limit
 - Flammable Liquids 3: Flammable liquids – Category 3
 - Acute Toxicity - Oral 4: Acute toxicity – Category 4
 - Skin Irritation 2: Skin corrosion/irritation – Category 2
 - Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
 - Sensitization - Skin 1: Skin sensitisation – Category 1
- *** Data compared to the previous version altered.**

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