# Safety Data Sheet
## acc. to OSHA HCS

Printing date 05/22/2025 Reviewed on 05/22/2025

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## 1 Identification

· **Product identifier**

· **Trade name: Enamelast™**

· **Article number:**
SDS 352-001.17R01, 71122, 1009274, 1001036, 1005983, 13784, 12280, 13454, 4352, 1006557, 1006179, 12550, 5154, 3380, 4344-P3, 5187, 2486, 5782, 2484, 5783, 5187-CA, 4362-CA, 4518-CA, 5188, 4352-CA, 4343-CA, 4528-CA, 6293, 4353-P3, 2485, 4353, 5786, 4822, 4344, 4362-CN, 4343-CN, 4528-CN, 4518-CN, 4363-P3, 4947, 5784, 4518, 5785, 4352-CN, 5187-CN, 4819, 4343, 4362, 5329, 4363, 4528-P3, 4518-JP, 4528, 4518-P3, 5787

· **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) : +1 (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:**
Resin acids and Rosin acids, hydrogenated, esters with glycerol
Bubble Gum Flavor
Sodium Fluoride
Isopulegol

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Trans-p-Menthan-3-One
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)**


Health = 2
Fire = 3
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**


Health = 2
Fire = 3
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 | ≥18-<40% |
| | Resin acids and Rosin acids, hydrogenated, esters with glycerol | ≥0-≤10% |
| 7681-49-4 | Sodium Fluoride | >1-<10% |
| 36653-82-4 | 1-Hexadecanol | >1-<10% |
| | Bubble Gum Flavor | ≥0-<5% |
| 5949-29-1 | Citric Acid Monohydrate | >0.25-≤3% |
| | Amaretto Flavor | ≥0-<5% |
| 89-78-1 | Menthol | ≥0-<5% |
| | Strawberry Flavor | ≥0-<5% |
| | 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:**
$CO_2$, 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 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.

## 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 section 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 Alcohol | |
|---|---|
| PEL | Long-term value: 1900 mg/m³, 1000 ppm |
| REL | Long-term value: 1900 mg/m³, 1000 ppm |
| STEL | Short-term value: 1000 mg/m³ |
| TLV | Short-term value: 1000 ppm<br>A3 |
| TWA | Short-term value: 1900 mg/m³ |
| **89-78-1 Menthol** | |
| WEEL | Short-term value: 19.2* mg/m³, 3* ppm<br>Long-term value: 6.4* mg/m³, 1* ppm<br>*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:** | Flammable. |
| · **Decomposition temperature:** | Not determined. |
| · **Ignition temperature:** | 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 | 965-1,040 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) |
| | 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:**
· **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 |

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· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **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) |
| **7681-49-4 Sodium Fluoride** | |
| EC50 | 272 mg/kg (Algae)<br>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.
· **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** Alcohols, flammable, toxic, n.o.s. (Ethyl Alcohol, Sodium fluoride)

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| | |
|---|---|
| · **IMDG, IATA** | ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol, SODIUM FLUORIDE) |
| · **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 MARPOL73/78 and the IBC Code** | Not Applicable. |
| · **Transport/Additional information:** | |
| · **DOT** | |
| · **Quantity limitations** | On passenger aircraft/rail: 1 L<br>On cargo aircraft only: 60 L |
| · **IMDG** | |
| · **Limited quantities (LQ)** | 1L |
| · **Excepted quantities (EQ)** | Code: E2<br>Maximum net quantity per inner packaging: 30 ml<br>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**
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 |
| | Resin acids and Rosin acids, hydrogenated, esters with glycerol | 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 |

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· **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

## 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** 05/22/2025 / -
· **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.**