

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

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

· **Product identifier**

· **Trade name:** Enamelast®

· **Article number:** 1006557, 1006179, 71122, 1001036

· **Index number:** SDS 352-001.11

· **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

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

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

· **Emergency telephone number:**

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

2 Hazards identification

· **Classification of the substance or mixture**

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



GHS02 flame

Flam. Liq. 3 H226 Flammable liquid and vapour.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Acute Tox. 4 H332 Harmful if inhaled.

Skin Irrit. 2 H315 Causes skin 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**

The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: Enamelast®

(Contd. of page 1)

are provided solely on a voluntary basis.

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**

Sodium Fluoride
Bubble Gum Flavor
D,L-Isomenthone
Trans-p-Menthan-3-One
(R)-P-Mentha-1,8-Diene
Orange Oil

· **Hazard statements**

H226 Flammable liquid and vapour.
H302+H332 Harmful if swallowed or if inhaled.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
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 label before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 Use explosion-proof electrical/ventilating/lighting equipment.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

EUH031 Contact with acids liberates toxic gas.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterisation:** Mixtures

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

· **Dangerous components:**

CAS: 64-17-5	Ethyl Alcohol	< 25%
EINECS: 200-578-6	Flam. Liq. 2, H225	

(Contd. on page 3)

GB2

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: Enamelast®

(Contd. of page 2)

CAS: 8050-15-5 EINECS: 232-476-2	Hydrogenated Rosin Aquatic Chronic 3, H412	< 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	5%
	Bubble Gum Flavor ⚠ Flam. Liq. 2, H225; ⚠ Repr. 2, H361; ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	< 5%
CAS: 89-78-1 EINECS: 201-939-0	Menthol ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	< 1%
	Strawberry Flavor ⚠ Flam. Liq. 3, H226; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	< 2%
CAS: 491-07-6 EINECS: 207-727-4	D,L-Isomenthone ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317	≤ 2.5%
CAS: 89-80-5 EINECS: 201-941-1	Trans-p-Menthan-3-One ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317	≤ 2.5%
CAS: 5989-27-5 EINECS: 227-813-5	(R)-P-Mentha-1,8-Diene ⚠ Flam. Liq. 3, H226; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317	≤ 2.5%
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%

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

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 not possible.

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

· **After eye contact:** Rinse opened eye for several minutes under running water.

· **After swallowing:** If swallowed in large quantities seek medical attention.

· **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 Firefighting measures

· **Extinguishing media**

· **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

· **Special hazards arising from the substance or mixture** No further relevant information available.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: Enamelast®

(Contd. of page 3)

- **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 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.
- **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

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

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

64-17-5 Ethyl Alcohol

WEL (Great Britain) Long-term value: 1920 mg/m³, 1000 ppm

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

(Contd. on page 5)

GB2

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: Enamelast®

(Contd. of page 4)

- **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 skin.
 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

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Viscous Liquid
Colour:	White
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

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: Enamelast®

(Contd. of page 5)

· Flammability (solid, gas):	Not applicable.
· 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:	1.03 g/cm ³
· 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.
· Solvent content:	
Organic solvents:	< 30 %
VOC (EC)	< 1%
Solids content:	<50.0 %
· 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:** Contact with acids releases toxic gases.
- **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 or if inhaled.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

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

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: Enamelast®

(Contd. of page 6)

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)
	8050-15-5 Hydrogenated Rosin	
Oral	LD50	>5,000 mg/kg (Guinea pig) >5,000 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)
5989-27-5 (R)-P-Mentha-1,8-Diene		
Oral	LD50	4,400 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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)
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)
7681-49-4 Sodium Fluoride		
	EC50	272 mg/kg (Algae) 98 mg/kg (daphnia)
	Algae Toxicity (static)	7 mg/l (Algae)

- **Persistence and degradability** No further relevant information available.

(Contd. on page 8)

GB2

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: Enamelast®

(Contd. of page 7)

- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological 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.
Harmful to aquatic organisms
- **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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

HP 3	Flammable
HP 6	Acute Toxicity
HP 10	Toxic for reproduction
HP 12	Release of an acute toxic gas
HP 14	Ecotoxic

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

14 Transport information

- **UN-Number**
- **ADR, IMDG, IATA** UNI986
- **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.

(Contd. on page 9)



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: Enamelast®

(Contd. of page 8)

· Label	3+6.1
· IMDG	
	
· Class	3 Flammable liquids.
· Label	3/6.1
· IATA	
	
· Class	3 Flammable liquids.
· Label	3 (6.1)
· Packing group	II
· ADR, IMDG, IATA	II
· Environmental hazards:	Not applicable.
· Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	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:	
· 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

GB2

(Contd. on page 10)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: **Enamelast®**

(Contd. of page 9)

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I**
Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.
- Product: None
- Contained substance: None.
- Substances in Candidate List (Art. 59 REACH): None.
- Substances subject to authorisation (Annex XIV REACH): None
- Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None
- Substances subject to the Rotterdam Convention: None.
- Substances subject to the Stockholm Convention: None.
- Healthcare controls: Information not available.
- **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**
- **REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3**
- **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**
- H225 Highly flammable liquid and vapour.
- H226 Flammable liquid and vapour.
- H301 Toxic if swallowed.
- H304 May be fatal if swallowed and enters airways.
- H310 Fatal in contact with skin.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H361 Suspected of damaging fertility or the unborn child.
- 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.
- **Department issuing SDS: Regulatory Affairs**
- **Contact: Customer Service**

(Contd. on page 11)

GB2

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.10.2018

Revision: 19.09.2018

Trade name: **Enamelast®**

(Contd. of page 10)

Abbreviations and acronyms:

ADR: Accord européen sur le transport 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)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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 Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 2: Reproductive toxicity – Category 2

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

GB2