

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 05/31/2013

SDS No : 352-001.5

Date Revised : 03/19/2015

Revision No : 4

Enamelast™**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : 2I/1001036
Product name : Enamelast™
Product description : 5% Sodium Fluoride Varnish

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Varnish

1.3. Details of the supplier of the safety data sheet**Manufacturer**

Ultradent Products, Inc.
 505 W. 10200 S.
 South Jordan, UT 84095

Distributor

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

1.4. Emergency telephone number

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

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Danger symbols : F,Xn

R phrases : R22

Classification according to Regulation (EC) No 1272/2008 [CLP]

Health : Acute Toxicity (Oral)

Physical : Flammable Liquids, Category 2

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : F Xn



Highly
flammable



Harmful

R&S statement(s) : R22: Harmful if swallowed.

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ULTRADENT
 PRODUCTS, INC.

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Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictogram(s)



Signal Word

: WARNING

Hazard statement(s)

: H302: Harmful if swallowed.
 H225: Highly flammable liquid and vapour.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response

: P370+P380+P375: In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.
 P305: IF IN EYES:
 P351: Rinse cautiously with water for several minutes.
 P337+P313: If eye irritation persists: Get medical advice/attention.
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.
 P332+P313: If skin irritation occurs: Get medical advice/attention.

Storage

: P273: Avoid release to the environment.

Disposal

: P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns

: Harmful if swallowed.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Synthetic Resin	68990-02-3	273-574-5	< 50	Xi; R36/37/38	Not classified
Ethyl Alcohol	64-17-5	200-578-6	< 15	F; R11	Flam. Liq., Cat. 2; H225
Sodium Fluoride	007681-49-4	231-667-8	≤ 5	T, Xi; R25; R32; R36/38	Acute Tox. (O), Cat. 3; Eye Irr., Cat. 2; Skin Irr., Cat. 2; H301; H315; H319
Methyl ester of hydrogenated rosin	8050-15-5	232-476--6	≤ 5	Xn; R52/53; R20	H412; H317
Citric Acid	77-92-9	201-069-9	≤ 3	Xi; R36/37/38; R22	H335; H314; H302; H315; H318

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

- Following eyes** : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes** : Irritating to eyes.
- Skin** : May cause skin irritation.
- Ingestion** : May be harmful if swallowed in large quantities.
- Inhalation** : None expected for this product.

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Enamelast™**4.3. Indication of any immediate medical attention and special treatment needed**

Notes to physician : Not Applicable

SECTION 5: Fire fighting measures**5.1. Extinguishing media**

Extinguishing media : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

Explosion hazards : Not Determined

Fire explosion : Not Determined

Sensitive to static discharge : Not Determined

Sensitivity to impact : Not Determined

5.3. Advice for firefighters

Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

Fire fighting equipment : Foam, dry chemical, carbon dioxide (CO₂).**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

General procedures : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small spill : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

Large spill : Remove all sources of ignition. Ventillate area of leak or spill. Pick up spill for recovery or disposal and place into sealed containers.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Handling : Keep away from heat, sparks and flame.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

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Specific end use(s) : Professional Dental Varnish

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Viscous substance

Colour : White

Odour : Flavor dependent

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Strong acids, strong bases, and oxidizing agents.

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

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

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SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

12.6. Other adverse effects

Environmental data : Biodegradable

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

UN number : 1986

14.2. UN proper shipping name

UN proper shipping name : Alcohols, Flammable, Toxic, n.o.s. (Ethyl alcohol/Fluoride mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 3(6.1)
Hazard classification : 3(6.1)

14.4. Packing group

Packing group : II

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

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ADR - road : N/A
 RID - rail : N/A
 IMDG - sea : N/A
 IATA - air : N/A

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : N/A

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R11: Highly flammable.
 R20: Harmful by inhalation.
 R22: Harmful if swallowed.
 R25: Toxic if swallowed.
 R32: Contact with acids liberates very toxic gas.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 R36/38: Irritating to eyes and skin.
 R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 H225: Highly flammable liquid and vapour.
 H301: Toxic if swallowed.
 H302: Harmful if swallowed.
 H314: Causes severe skin burns and eye damage.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.
 H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 02/26/2015 SDS. Revised: **Section 1:** . **Section 2:** . **Section 10:** STABLE. **Section 16:** GENERAL STATEMENTS.

General statements : N/A= Not Applicable

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the

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information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.