

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 05/31/2013  
SDS No : 352-001.6  
Date Revised : 03/23/2016  
Revision No : 5

## Enamelast™ (All Flavors)

### SECTION 1 : Identification of the substance/preparation and of the company/undertaking

#### 1.1. Product identifier

**Product code** : 6A/1004438, 6B/1004439, 6C/1004440, 2I/1001036  
**Product name** : Enamelast™ (All Flavors)  
**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), Category 3

**Physical** : Flammable Liquids, Category 2

#### 2.2. Label elements

##### Classification according to Directive 1999/45/EC

**Hazard pictogram(s)** : F  
  
Highly  
flammable Xn  
  
Harmful

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

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

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Hazard pictogram(s) :



Signal Word :

DANGER

Hazard statement(s) :

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

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

: Highly Flammable

## SECTION 3: Composition / information on ingredients

### 3.1. Substances

Not Applicable

### 3.2. Mixtures

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; EUH 210
Sodium Fluoride	007681-49-4	231-667-8	≤ 5	T; Xi; R25; R32; R36/38	Eye Irr., Cat. 2; Skin Irr., Cat. 2; Acute Tox. (O), Cat. 3; EUH032; H301;

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					H315; H319
Methyl ester of hydrogenated rosin	8050-15-5	232-476-2	≤ 5	Xn; R52/53; R20	Aquatic Chronic, Cat. 3; H412
Citric Acid	77-92-9	201-069-1	≤ 3	Xi; R36/37/38; R22	Eye Irr., Cat. 2A; H319

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.

##### 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** : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

##### 5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : 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.

#### SECTION 6: Accidental release measures

##### 6.1. Personal precautions, protective equipment and emergency procedures

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

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**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**

**General procedures** : Avoid contact with eyes, skin and clothing.

**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)**

**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**

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**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** : Heat, flames and sparks. Extremes of temperature and direct sunlight.

**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.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Toxicity** : Not Determined

**Aquatic toxicity (acute)**

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

**96-hour EC<sub>50</sub>** : Not Determined

**Notes** : Do not allow to enter sewers or drains that may lead to waterways.

**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**

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### 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

**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.

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Acute Tox. (O), Cat. 3: Acute Toxicity (Oral), Category 3  
Aquatic Chronic, Cat. 3: Chronic Hazards to the Aquatic Environment, Category 3  
Eye Irr., Cat. 2A: Eye Irritation, Category 2A  
Eye Irr., Cat. 2: Eye Irritation, Category 2  
Flam. Liq., Cat. 2: Flammable Liquids, Category 2  
Skin Irr., Cat. 2: Skin Irritation, Category 2  
EUH 210: Safety data sheet available on request.  
EUH032: Contact with acids liberates very toxic gas.  
H225: Highly flammable liquid and vapour.  
H301: Toxic if swallowed.  
H315: Causes skin irritation.  
H319: Causes serious eye irritation.  
H412: Harmful to aquatic life with long lasting effects.

**Prepared by**

: Anu Kattoju

**Revision summary**

: This SDS replaces the 03/19/2015 SDS. Revised: **Section 1:** MSDS No, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 7:** GENERAL PROCEDURES. **Section 10:** CONDITIONS TO AVOID. **Section 12:** ECOTOXICOLOGICAL INFORMATION, AQUATIC TOXICITY (ACUTE) - Notes.

**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 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.