

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 5/31/2013

SDS No : 352-001.3

Date Revised : 6/23/2014

Revision No : 2

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 Use 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

UP Dental GmbH
 Am Westhover Berg 30
 51149 Cologne Germany
 Email: info@updental.de
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

Danger symbols : F, Xn
R phrases : R22

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.

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

Hazard pictogram(s) :  
 Flame Exclamation mark

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Signal Word : WARNING
Hazard statement(s) : H302: Harmful if swallowed.
 H223: Flammable material.

2.3. Other hazards

Immediate concerns : Harmful if swallowed.

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
Synthetic Resin	68990-02-3	273-574-5	< 50	Xi; R36/37/38
Ethyl Alcohol	64-17-5	200-578-6	< 15	F; R11
Sodium Fluoride	007681-49-4	231-667-8	<= 5	T, Xi; R25; R32; R36/38
Methyl ester of hydrogenated rosin	8050-15-5	232-476--6	<= 5	Xn; R52/53; R20
Citric Acid	77-92-9	201-069-9	<= 3	Xi; R36/37/38; R22

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.

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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

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

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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 : S36/37: 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

Stable : Yes

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Hazardous polymerization : No

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

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Dermal LD₅₀ : Not Determined
 Oral LD₅₀ : Not Determined
 Inhalation LC₅₀ : Not Determined

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

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

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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 : Not Determined

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.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 10/15/2013 SDS. Revised: **Section 1:** GENERAL USE, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** INGESTION, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INGESTION, INHALATION, SKIN). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, WATER SPILL, . **Section 7:** SHELF LIFE, STORAGE, . **Section 8:** . **Section 9:** PERCENT VOLATILE. **Section 10:** HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABILITY, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat)). **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀). **Section 14:** AIR (ICAO/IATA) - SPECIAL PROVISIONS ROAD AND RAIL (ADR/RID) - SPECIAL PROVISIONS VESSEL (IMO/IMDG) (SPECIAL PROVISIONS), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS. **Section 15:** RoHS, SECTION 15: Regulatory

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information. **Section 16:** GENERAL STATEMENTS.

General statements

: NA = Not Applicable

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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.