

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 10/27/2006

SDS No : 65-001.8

Date Revised : 10/25/2016

Revision No : 9

PrimaDry®

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

1.1. Product identifier

Product code : PY/10955
 Product name : PrimaDry®
 Product description : Dental drying and priming agent.

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

Relevant identified uses : Professional Dental Priming Agent

1.3. Details of the supplier of the safety data sheet

Manufacturer

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

EC Responsible Person

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 Regulation(EC) No 1272/2008 [CLP]

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

Health : Eye Irritation, Category 2
 Skin Irritation, Category 2
 Acute Toxicity (Inhalation), Category 1

Environmental : Flammable Liquids, Category 2

2.2. Label elements

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

Hazard pictogram(s) :



Flame



Exclamation mark

Signal Word : DANGER

Hazard statement(s) : H225: Highly flammable liquid and vapour.
 H319: Causes serious eye irritation.

Precautionary statement(s)

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Prevention	: P280: Wear protective gloves/protective clothing/eye protection/face protection. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P370+P378: In case of fire: Use Water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish.
Response	: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P315: Get immediate medical advice/attention. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P313: Get medical advice/attention.
Storage	: P273: Avoid release to the environment. P233: Keep container tightly closed. P403+P235: Store in a well-ventilated place. Keep cool. P243: Take action to prevent static discharges. P241: Use explosion-proof [electrical/ventilating/lighting] equipment. P242: Use non-sparking tools.
Disposal	: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

2.3. Other hazards

Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Regulation (EC) No 1272/2008 [CLP]
Ethyl Alcohol	64-17-5	200-578-6	< 100	Flam. Liq., Cat. 2; Eye Irr., Cat. 2; Skin Irr., Cat. 2; STOT SE, Cat. 3; H225; H319

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes	: Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.
Following skin	: Remove contaminated clothing. Wash affected area with large quantities of water for at least five minutes. Seek medical assistance if necessary.
Following ingestion	: If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center if you feel

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unwell.

Following inhalation : Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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

Eyes : Causes eye irritation.
Skin : May cause slight irritation.
Ingestion : May cause serious damage.
Inhalation : High concentrations may cause central nervous system effects characterized by nausea, headache, dizziness, unconsciousness and coma. Causes respiratory tract irritation. May cause narcotic effects in high concentration. Vapors may cause dizziness or suffocation.

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 : Water spray, alcohol-resistant foam, dry chemical or carbon dioxide

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Carbon monoxide

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.

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 : Absorb with inert, damp non-combustible material, then flush area with water.

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 : Keep in a cool, well ventilated place in a tightly closed container.

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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 Priming Agent

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Ethyl Alcohol CAS: 64-17-5

Control Parameters	Exposure Limits
OSHA PEL General Industry	1000 ppm (1900 mg/m ³) TWA
OSHA PEL - Construction Industry	1000 ppm (900 mg/m ³) TWA
OSHA PEL Shipyard Employment	1000 ppm(1900 mg/m ³) TWA
NIOSH REL	1000 ppm(1900 mg/m ³) TWA
ACGIH TLV	1000 ppm(1880 mg/m ³) STEL
CAL/OSHA PEL	1000 ppm(1900 mg/m ³) TWA

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. In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : Colorless to slight yellow

Odour : Ethanol

Freezing temperature : -114°C

Boiling temperature : 78°C

Flash point : 13°C (56°F) Closed Cup

Evaporation rate : Specific data not available - expected to be rapid.

Flammability (solid, gas) : Flammable

Flammable limits : 3.3%(V) to 19%(V)

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Vapor pressure	: 59.5 hPa at 20°C
Vapor density	: 1.6
Density	: 0.785 at 25°C
Solubility in water	: Completely soluble
Weight per volume	: 46.07 g/mol

9.2. Other information

Percent volatile	: Not Determined
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	: Stable
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10.2. Chemical stability

Chemical stability	: Stable when stored and handled under recommended conditions.
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10.3. Possibility of hazardous reactions

Hazardous polymerization	: None
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10.4. Conditions to avoid

Conditions to avoid	: Heat, flames, and ignition sources
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10.5. Incompatible materials

Incompatible materials	: None known.
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10.6. Hazardous decomposition products

Hazardous decomposition products	: None known.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD ₅₀	: Not able to calculate ATE mix(dermal) due to lack of data on the components.
Oral LD ₅₀	: > 3400 mg/kg Mouse
Inhalation LC ₅₀	: 0.039 mg/L/4H Mouse
Other information	: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute)	: Do not allow to enter sewers or drains that may lead to waterways.
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12.2. Persistence and degradability

Persistence and degradability	: Not classified
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12.3. Bioaccumulative potential

Bioaccumulative potential	: Not classified
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PrimaDry®**12.4. Mobility in soil**

Mobility in soil : Not Available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

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 : 1987

14.2. UN proper shipping name

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

14.3. Transport hazard class(es)

Primary hazard class/division : 3

Hazard classification : 3

14.4. Packing group

Packing group : II

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

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

Transport in bulk : NAP

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

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Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

SECTION 16: Other information

Relevant H-statements (number and full text) : Eye Irr., Cat. 2: Eye Irritation, Category 2
 Flam. Liq., Cat. 2: Flammable Liquids, Category 2
 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 H225: Highly flammable liquid and vapour.
 H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 04/27/2015 SDS. Revised: **Section 1**: Date-Revised.

General statements : NAP = Not Applicable
 NE = Not Established
 TLV = Threshold Limit Value
 PEL = Permittable exposure limits
 MAK = Maximum Workplace Concentration
 STEL = Short-term exposure limit
 STEV = Short-term exposure value
 TWA = Time Weighted Average
 PPE = Personal Protective Equipment

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.