

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

Printing date 20.05.2019

Revision: 09.04.2019

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

- **Product identifier**
- **Trade name:** PrimaDry™
- **Article number:** 10955
- **Index number:** SDS 65-001.09
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Priming Agent
- **Application of the substance / the mixture** Professional Dental Priming Agent
- **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**



Flam. Liq. 2 H225 Highly flammable liquid and vapour.



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

- **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 are provided solely on a voluntary basis.
- **Hazard pictograms** GHS02, GHS07
- **Signal word** Danger

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- **Hazard statements**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

- **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.

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.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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 EINECS: 200-578-6	Ethyl Alcohol	 Flam. Liq. 2, H225	>50-≤100%
	Trade Secret	 Skin Corr. 1A, H314	≤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.

- **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

- **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- **After swallowing:** If symptoms persist consult doctor.

- **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.

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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** Carbon monoxide (CO)
- **Advice for firefighters:**
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** 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:** Keep away from heat and direct sunlight.
- **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:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
See product labelling.
Keep container tightly sealed.
Store in cool, dry conditions in well - sealed receptacles.
- **Specific end use(s)** Professional Dental Priming Agent

8 Exposure controls/personal protection

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

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- **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/m ³ , 1000 ppm

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

- **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 eyes and skin.

- **Respiratory protection:** Not required.

- **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: Liquid

Colour: Yellow tint

- **Odour:** Alcohol-like

- **Odour threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/freezing point: -100 °C

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Initial boiling point and boiling range:	78 °C
· Flash point:	13 °C
· Flammability (solid, gas):	Not applicable.
· Ignition temperature:	363 °C
· 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:	3.3 Vol %
Upper:	19 Vol %
· Vapour pressure at 20 °C:	552 hPa
· Density at 20 °C:	0.79 g/cm ³
· Relative density	Not determined.
· Vapour density at 20 °C	1.6 g/cm ³
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water at 20 °C:	1,000 g/l
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
VOC (EC)	0.00 %
· 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:** Flammable.
- **Conditions to avoid:**
 - Ignition sources
 - Sparks
 - Flames
 - Heat
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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· **LD/LC50 values relevant for classification:**

64-17-5 Ethyl Alcohol

Oral	LD50	5,600 mg/kg (Guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
Inhalative	LC50 Fish	>10,000 mg/l (Fish)
	LC50/4 h	39 mg/l (mouse) 20,000 mg/l (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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)
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- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **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.
- **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** Do not allow product to reach sewage system.

· **European waste catalogue**

HP 3	Flammable
HP 4	Irritant - skin irritation and eye damage

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

14 Transport information

· UN-Number · ADR, IMDG, IATA	UNI987
· UN proper shipping name · ADR · IMDG, IATA	1987 ALCOHOLS, N.O.S. (Ethyl Alcohol) ALCOHOLS, N.O.S. (Ethyl Alcohol)
· Transport hazard class(es) · ADR, IMDG, IATA	
	
· Class · Label	3 Flammable liquids. 3
· Packing group · ADR, IMDG, IATA	II
· Environmental hazards:	Not applicable.
· Special precautions for user · Danger code (Kemler): · EMS Number: · Stowage Category	Warning: Flammable liquids. 33 F-E,S-D B
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category · Tunnel restriction code	2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1987 ALCOHOLS, N.O.S. (ETHYL ALCOHOL), 3, II

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15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **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.
H314 Causes severe skin burns and eye damage.
- **Department issuing SDS:** Regulatory Affairs
- **Contact:** Customer Service
- **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
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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