

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

Printing date 12.06.2020

Revision: 10.10.2018

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

- **Product identifier**
- **Trade name:** UltraSeal XT™ plus
- **Article number:** XA/73401, XB/13560, XR/56303, XT/10952
- **Index number:** SDS: 25-001.16
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Pit and Fissure Sealant
- **Application of the substance / the mixture** Professional Dental Pit and Fissure Sealant
- **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**



Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Triethylene Glycol Dimethacrylate
Diurethane Dimethacrylate
Organophosphine Oxide
- **Hazard statements**
H317 May cause an allergic skin reaction.

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· 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.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P272 Contaminated work clothing should not be allowed out of the workplace.
 P280 Wear protective gloves.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 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: 109-16-0 EINECS: 203-652-6	Triethylene Glycol Dimethacrylate ⚠ Skin Sens. 1, H317	>10-≤25%
CAS: 72869-86-4 EINECS: 276-957-5	Diurethane Dimethacrylate ⚠ Skin Sens. 1, H317	>2.5-≤10%
CAS: 1344-28-1 EINECS: 215-691-6	Aluminium Oxide substance with a Community workplace exposure limit	>2.5-≤10%
CAS: 868-77-9 EINECS: 212-782-2	2-Hydroxyethyl Methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≤2.5%
	Amine Methacrylate ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≤2.5%
CAS: 162881-26-7 ELINCS: 423-340-5	Organophosphine Oxide ⚠ Skin Sens. 1, H317; Aquatic Chronic 4, H413	≤2.5%
CAS: 10163-15-2 EINECS: 233-433-0	Sodium Monofluorophosphate ⚠ Acute Tox. 4, H302	0.1%

· **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:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:** Rinse opened eye for several minutes under running water.

· **After swallowing:** If swallowed in large quantities seek medical attention.

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- **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.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Foam, dry chemical, carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
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:**
Avoid contact with eyes, skin, and clothing. Use suitable protective equipment.
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** See product labeling.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See product labelling.
- **Specific end use(s)** Professional Dental Pit and Fissure Sealant

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:**

1344-28-1 Aluminium Oxide	
WEL (Great Britain)	Long-term value: 10* 4** mg/m ³ *inhalable dust **respirable dust
79-41-4 Methacrylic Acid	
WEL (Great Britain)	Short-term value: 143 mg/m ³ , 40 ppm Long-term value: 72 mg/m ³ , 20 ppm

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

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **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:** Not required.

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Liquid

Colour: Shade dependent

- **Odour:** Acrylic

- **Odour threshold:** Not determined.

- **pH-value:** Not applicable (non-aqueous)

- **Change in condition**

Melting point/freezing point: Undetermined.

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Initial boiling point and boiling range: Undetermined.	
· Flash point:	>100 °C
· Flammability (solid, gas):	Not determined.
· Ignition temperature:	445 °C
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure at 20 °C:	0 hPa
· Density at 20 °C:	1.7-1.8 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Solids content:	<60.0 %
· 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:** No dangerous reactions known.
- **Conditions to avoid:** Avoid light exposure
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

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

· LD/LC50 values relevant for classification:		
109-16-0 Triethylene Glycol Dimethacrylate		
Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)

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Dermal	LD50	>2,000 mg/kg (mouse)
72869-86-4 Diurethane Dimethacrylate		
Oral	LD50	>5,000 mg/kg (rat)
1344-28-1 Aluminium Oxide		
Oral	LD50	>5,000 mg/kg (rat)
79-41-4 Methacrylic Acid		
Oral	LD50	1,250 mg/kg (mouse)
		1,060 mg/kg (rat)
		1,200 mg/kg (rabbit)
Dermal	LD50	86 mg/l (Fish)
		1,000 mg/kg (Guinea pig)
Inhalative	LC50/4 h	500 mg/kg (rabbit)
		7.1 mg/l (rat)
162881-26-7 Organophosphine Oxide		
Oral	LD50	>2,000 mg/kg (rat)
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **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:

109-16-0 Triethylene Glycol Dimethacrylate	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
EC50	>100 mg/l (Algae) (Toxicity to algae)
72869-86-4 Diurethane Dimethacrylate	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
EC50	>0.6 mg/l (Algae) (Toxicity to algae)
	>1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)
79-41-4 Methacrylic Acid	
EC50	<180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
EC50	45 mg/l (Algae) (Toxicity to algae)

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162881-26-7 Organophosphine Oxide

EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to algae)

- **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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

HP8	Corrosive
HP13	Sensitising

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

14 Transport information

· UN-Number	
· ADR, ADN, IMDG, IATA	not regulated
· UN proper shipping name	
· ADR, ADN, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADR, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.

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· UN "Model Regulation": not regulated

15 Regulatory information

· **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**

- H302 Harmful if swallowed.
- H312 Harmful in contact with skin.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H413 May cause long lasting harmful effects to aquatic life.

· **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)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Acute Tox. 4: Acute toxicity - oral – Category 4
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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Printing date 15.06.2020

Revision: 03.10.2018

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

- **Product identifier**
- **Trade name:** Ultra-Etch™ & Opal™ Etch
- **Article number:** 10947
- **Index number:** SDS 7-001.20
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Acid Etching Solution
- **Application of the substance / the mixture** Professional Dental Acid Etching Solution
- **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**



GHS05 corrosion

Skin Corr. 1B H314 Causes severe skin burns and eye damage.



GHS07

Acute Tox. 4 H332 Harmful if inhaled.

- **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** GHS05, GHS07
- **Signal word** Danger

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Trade name: Ultra-Etch™ & Opal™ Etch

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- **Hazard-determining components of labelling:**

Phosphoric Acid

- **Hazard statements**

H332 Harmful if inhaled.

H314 Causes severe skin burns and eye damage.

- **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.

P260 Do not breathe dusts or mists.

P264 Wash thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

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

P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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.

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

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

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: 7664-38-2 EINECS: 231-633-2	Phosphoric Acid ⚠ Acute Tox. 1, H330; ⚠ Met. Corr. 1, H290; Skin Corr. 1B, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302	<40%
	Dimethicone ⚠ Repr. 2, H361f; STOT RE 2, H373	<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.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

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- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
If swallowed in large quantities seek medical attention.
Drink plenty of water and provide fresh air. Call for a doctor immediately.
- **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.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Dry Chemical
Carbon dioxide
Alcohol resistant foam
Water spray
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture**
Phosphine, oxides of phosphorous, hydrogen gas
During heating or in case of fire poisonous gases are produced.
- **Advice for firefighters:**
General: Evacuate all personnel.
Use fire extinguishing methods suitable to surrounding conditions.
- **Protective equipment:**
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
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).
Use neutralising agent.
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:**
Safety glasses should be used by the patient and doctor. Use equipment for eye protection tested and approved under appropriate standards such as ANSI Z87.1

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Trade name: Ultra-Etch™ & Opal™ Etch

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- Avoid contact with eyes, skin, and clothing.
- Ensure good ventilation/exhaustion at the workplace.
- Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
 - Keep ignition sources away - Do not smoke.
 - Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
 - Requirements to be met by storerooms and receptacles:**
 - Store in a cool location.
 - Store only in the original receptacle.
 - Provide ventilation for receptacles.
 - Information about storage in one common storage facility:**
 - Store away from water.
 - Store away from metals.
 - Further information about storage conditions:**
 - Protect from heat and direct sunlight.
 - Store in a cool place.
 - See product labelling.
 - Keep container tightly sealed.
- **Specific end use(s)** Professional Dental Acid Etching Solution

8 Exposure controls/personal protection

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

- **Ingredients with limit values that require monitoring at the workplace:**

7664-38-2 Phosphoric Acid

<i>WEL (Great Britain)</i>	Short-term value: 2 mg/m ³ Long-term value: 1 mg/m ³
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- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 - Do not inhale gases / fumes / aerosols.
 - Do not eat or drink while working.
 - When using do not smoke.
 - 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:**
 - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

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Trade name: Ultra-Etch™ & Opal™ Etch

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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:**

Safety glasses should be used and by the patient and doctor. Use equipment for eye protection tested and approved under appropriate standards such as ANSI Z87.1



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Gel
· Colour:	Blue
· Odour:	Odourless
· Odour threshold:	Not determined.

· **pH-value at 20 °C:** <1

· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	100 °C

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· Density at 20 °C:	1.3 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

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Trade name: Ultra-Etch™ & Opal™ Etch

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· Solubility in / Miscibility with water:	Not miscible or difficult to mix.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Water:	<60 %
VOC (EC)	0.00 %
· Solids content:	<20.0 %
· Other information	Refractive Index 34-37 Brix

10 Stability and reactivity

- **Reactivity** Stable
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
Water, Moist Air
Extreme heat and open flames.
- **Incompatible materials:** Strong caustics, most metals
- **Hazardous decomposition products:** Phosphine, oxides of phosphorous, hydrogen gas
- **Additional information:**
Reacts with bases to form phosphate salts and is corrosive (especially when hot) to many metals and alloys. Liberates explosive hydrogen gas when reacting with chlorides and stainless steel, and reacts violently with sodium tetrahydroborate. Forms flammable gases with sulfides, mercaptans, cyanides and aldehydes. Also forms toxic fumes with cyanides, sulfides, fluorides, organic peroxides and halogenated organics

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
Harmful if inhaled.

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

ATE (Acute Toxicity Estimates)

Oral	LD50	4,358 mg/kg (rat)
Inhalative	LC50/4 h	0.92 mg/l

7664-38-2 Phosphoric Acid

Oral	LD50	1,530 mg/kg (rat)
Dermal	LD50	2,740 mg/kg (rabbit)
Inhalative	LC50/4 h	0.42225 mg/l (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.

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Trade name: Ultra-Etch™ & Opal™ Etch

(Contd. of page 6)

- **Serious eye damage/irritation**
Causes severe skin burns and eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenity, 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:** No further relevant information available.
- **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.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.
- **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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

HP6	Acute Toxicity
HP8	Corrosive

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

14 Transport information

- **UN-Number**
- **ADR, IMDG, IATA** UN1805

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Trade name: Ultra-Etch™ & Opal™ Etch

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<ul style="list-style-type: none"> · UN proper shipping name · ADR · IMDG, IATA 	<p>1805 PHOSPHORIC ACID, SOLUTION mixture PHOSPHORIC ACID, SOLUTION mixture</p>
<ul style="list-style-type: none"> · Transport hazard class(es) · ADR, IMDG, IATA 	
	
<ul style="list-style-type: none"> · Class · Label 	<p>8 Corrosive substances. 8</p>
<ul style="list-style-type: none"> · Packing group · ADR, IMDG, IATA 	<p>III</p>
<ul style="list-style-type: none"> · Environmental hazards: 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Segregation groups · Stowage Category · Segregation Code 	<p>Warning: Corrosive substances. 80 F-A,S-B Acids A SG36 Stow "separated from" SGG18-alkalis. SG49 Stow "separated from" SGG6-cyanides</p>
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: 	
<ul style="list-style-type: none"> · ADR · Limited quantities (LQ) · Excepted quantities (EQ) · Transport category · Tunnel restriction code 	<p>5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml 3 E</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> · UN "Model Regulation": 	<p>UN 1805 PHOSPHORIC ACID, SOLUTION MIXTURE, 8, III</p>

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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Trade name: Ultra-Etch™ & Opal™ Etch

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· **Chemical safety assessment:**

Device is a strong acid and is extremely toxic. It is to be used only as directed with PPE, and only by licensed dental professionals.

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**

H290 May be corrosive to metals.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

H361f Suspected of damaging fertility.

H373 May cause damage to organs through prolonged or repeated exposure.

· **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

Met. Corr. 1: Corrosive to metals – Category 1

Acute Tox. 4: Acute toxicity - oral – Category 4

Acute Tox. 1: Acute toxicity - inhalation – Category 1

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Repr. 2: Reproductive toxicity – Category 2

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

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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 65-001.10
- **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.
STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

- **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

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Trade name: PrimaDry™

(Contd. of page 1)

· **Signal word** *Danger*· **Hazard statements**H225 *Highly flammable liquid and vapour.*H315 *Causes skin irritation.*H319 *Causes serious eye irritation.*H335-H336 *May cause respiratory irritation. May cause drowsiness or dizziness.*· **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.*P240 *Ground and bond container and receiving equipment.*P241 *Use explosion-proof [electrical/ventilating/lighting] equipment.*P242 *Use non-sparking tools.*P243 *Take action to prevent static discharges.*P261 *Avoid breathing dust/fume/gas/mist/vapours/spray.*P264 *Wash thoroughly after handling.*P271 *Use only outdoors or in a well-ventilated area.*P280 *Wear protective gloves/protective clothing/eye protection/face protection.*P301+P312 *IF SWALLOWED: Call a doctor if you feel unwell.*P303+P361+P353 *IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].*P304+P341 *IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.*P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*P332+P313 *If skin irritation occurs: Get medical advice/attention.*P362+P364 *Take off contaminated clothing and wash it before reuse.*P337+P313 *If eye irritation persists: Get medical advice/attention.*P370+P378 *In case of fire: Use for extinction: CO₂, powder or water spray.*P403+P233 *Store in a well-ventilated place. Keep container tightly closed.*P403+P235 *Store in a well-ventilated place. Keep cool.*P405 *Store locked up.*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; Eye Dam. 1, H318	<1%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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Trade name: PrimaDry™

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4 First aid measures

- **Description of first aid measures**

- **General information:**

Take proper precautions to ensure your own health and safety before attempting rescue and providing first aid. Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area. Immediately remove any clothing soiled by the product.

- **After inhalation:**

Seek medical treatment in case of complaints.

Give oxygen or artificial respiration as needed.

Supply fresh air.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:**

If skin irritation continues, consult a doctor.

Launder clothing before reuse.

Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:**

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

- **After swallowing:**

Do NOT induce vomiting.

If vomiting does occur, have victim lean forward to prevent aspiration.

Rinse mouth with water.

Seek medical treatment.

Never give anything by mouth to an unconscious person.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed**

Symptoms vary with alcohol level of the blood. Mild alcohol intoxication occurs at blood levels between 0.05-0.15%. Approximately 25% of individuals show signs of intoxication at these levels. Above 0.15% the person is definitely under the influence of ethanol; 50-95% of individuals are clinically intoxicated at these levels. Severe poisoning occurs when the blood ethanol level is 0.3-0.5%. Above 0.5% the individual will be comatose and death can occur. The unabsorbed ethanol should be removed by gastric lavage after intubating the patient to prevent aspiration. Avoid the use of depressant drugs or the excessive administration of fluids.

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Firefighting measures

- **Extinguishing media**

- **Suitable extinguishing agents:**

Water fog

Alcohol resistant foam

Water spray

Carbon dioxide

Dry Chemical

- **Special hazards arising from the substance or mixture**

Carbon monoxide (CO)

May produce a floating fire hazard.

Static ignition hazard can result from handling and use.

Vapors may travel to source of ignition and flash back.

Vapors may settle in low or confined spaces.

Alcohols burn with a pale blue flame which may be extremely hard to see under normal lighting conditions.

Personnel may only be able to feel the heat of the fire without seeing flames. Extreme caution must be exercised in fighting alcohol fires. Fight fire from maximum distance or use unmanned hose holders or monitor nozzles. Cool

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Trade name: PrimaDry™

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containers with flooding quantities of water until well after fire is out. Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank. Always stay away from tanks engulfed in fire.

- **Advice for firefighters:**

- **Protective equipment:**

Wear self-contained respiratory protective device.

Wear fully protective suit.

- **Additional information** Cool endangered receptacles with water spray.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**

Do not inhale vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas.

Wear protective equipment. Keep unprotected persons away.

- **Environmental precautions:**

Stop leak. Contain spill if possible and safe to do so.

Do not allow to enter sewers/ surface or ground water.

- **Methods and material for containment and cleaning up:**

Highly flammable liquid. Eliminate all sources of ignition. All equipment used when handling this product must be grounded. A vapor suppressing foam may be used to reduce vapors. Do not touch or walk through spilled material. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations. Use clean non-sparking tools to collect absorbed material.

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:**

Avoid contact with eyes, skin, and clothing.

Do not inhale vapor or mist.

Open and handle container with care.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- **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:**

Metal containers involved in the transfer of this material should be grounded and bonded.

Store in a cool location.

- **Information about storage in one common storage facility:** Store away from flammable substances.

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Trade name: **PrimaDry™**

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- **Further information about storage conditions:**
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Consult local fire codes for additional storage information.
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.
- **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
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- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Observe good industrial hygiene practices.
Ensure that washing facilities are available at the work place.
Electrical equipment should be grounded and confirm to applicable electrical code.
When using do not smoke.
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:**
Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**
Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product.
Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.
Wash and dry 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.

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· **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:**

Maintain eye wash fountain and quick-drench facilities in work area.

Use equipment approved by appropriate government standards, such as NIOSH (US) or EN166 (EU)

Face protection

Use chemical safety goggles and/or a full face shield where splashing is possible.



Tightly sealed goggles

· **Body protection:**

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

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
· 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

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Trade name: PrimaDry™

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· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
VOC (EC)	99.00 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity Stable**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:**
Vapors may form explosive mixture with air.
Flammable.
- **Conditions to avoid:**
Direct sunlight
Extreme temperature
Sparks
Flames
Heat
- **Incompatible materials:**
Alkali metals
Strong Inorganic Acids
Peroxides
Oxidizing Agents
Ammonia
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological information

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

· **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.

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Revision: 09.04.2019

Trade name: PrimaDry™

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- **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**
May cause respiratory irritation. May cause drowsiness or dizziness.
- **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)
----------------	--------------------

- **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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

HP3	Flammable
-----	-----------

HP4	Irritant - skin irritation and eye damage
-----	---

- **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**

1987 ALCOHOLS, N.O.S. (Ethyl Alcohol)

- **IMDG, IATA**

ALCOHOLS, N.O.S. (Ethyl Alcohol)

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Trade name: PrimaDry™

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· Transport hazard class(es)

· ADR, IMDG, IATA



· Class

3 Flammable liquids.

· Label

3

· Packing group

II

· ADR, IMDG, IATA

· Environmental hazards:

Not applicable.

· Special precautions for user

Warning: Flammable liquids.

· Hazard identification number (Kemler code):

33

· EMS Number:

F-E,S-D

· Stowage Category

B

· Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

· Transport/Additional information:

· ADR

· Limited quantities (LQ)

1L

· Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· Transport category

2

· Tunnel restriction code

D/E

· IMDG

· Limited quantities (LQ)

1L

· Excepted quantities (EQ)

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

15 Regulatory information

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

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· 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

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

Printing date 23.03.2020

Revision: 09.04.2019

Trade name: **PrimaDry™**

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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.
H318 Causes serious 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 Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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