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

Printing date 15.06.2020 *Revision: 08.10.2018*

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

· **Product identifier**

· **Trade name: Ultradent™ Porcelain Etch**

· **Article number:** 10324
· **Index number:** SDS 4-001.16
· **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 Westhover 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**

GHS06 skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.
Acute Tox. 2 H310 Fatal in contact with skin.
Acute Tox. 3 H331 Toxic if inhaled.

GHS05 corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

· **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.

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· **Hazard pictograms** GHS05, GHS06
· **Signal word** Danger

· **Hazard-determining components of labelling:**
Hydrofluoric Acid
· **Hazard statements**
H301+H331 Toxic if swallowed or if inhaled.
H310 Fatal in contact with skin.
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.
P262 Do not get in eyes, on skin, or on clothing.
P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P321 Specific treatment (see on this label).
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.
P311 Call a POISON CENTER/doctor.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P361+P364 Take off immediately all contaminated clothing and wash it before reuse.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.
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: 7664-39-3 EINECS: 231-634-8	Hydrofluoric Acid Acute Tox. 2, H300; Acute Tox. 1, H310; Acute Tox. 2, H330; Skin Corr. 1A, H314	>2.5-≤10%

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

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4 First aid measures

· ***Description of first aid measures***
· ***General information:***
Immediately remove any clothing soiled by the product.
Remove breathing equipment only after contaminated clothing have been completely removed.
In case of irregular breathing or respiratory arrest provide artificial respiration.
· ***After inhalation:***
Supply fresh air or oxygen; call for doctor.
In case of unconsciousness place patient stably in side position for transportation.
· ***After skin contact:***
Rub in Ca-gluconate solution or Ca-gluconate gel immediately.
Immediately remove all soiled and contaminated clothing.
Seek immediate medical advice.
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:***
Do not induce vomiting; call for medical help immediately.
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:***
Foam, dry chemical, carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
· ***Special hazards arising from the substance or mixture***
During heating or in case of fire poisonous gases are produced.
· ***Advice for firefighters:***
· ***Protective equipment:*** *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:*** *No special measures required.*
· ***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.

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7 Handling and storage

· **Handling:**
· **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
· **Information about fire - and explosion protection:** Keep respiratory protective device available.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** Unsuitable material for receptacle: glass or ceramic.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
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:**	
7664-39-3 Hydrofluoric Acid	
WEL (Great Britain)	Short-term value: 2.5 mg/m³, 3 ppm Long-term value: 1.5 mg/m³, 1.8 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.
Store protective clothing separately.
Avoid contact with the eyes.
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

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:**

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:	Yellow
· **Odour:**	Acidic
· **Odour threshold:**	Not determined.
· **pH-value:**	< 1.0
· **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:**	1.1-1.2 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **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:	<100 %

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VOC (EC)	0.00 %
Solids content:	<21.0 %
· **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:**
Reacts with organic substances.
Reacts with strong alkali.
Reacts with acids.
Reacts with certain metals.
· **Conditions to avoid:** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:**
Hydrogen fluoride
Hydrogen
Corrosive gases/vapours

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity**
Toxic if swallowed or if inhaled.
Fatal in contact with skin.

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

ATE (Acute Toxicity Estimates)

Oral	LD50	51.4-58.2 mg/kg
Dermal	LD50	51.4-58.2 mg/kg
Inhalative	LC50/4 h	5.14-5.82 mg/l

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

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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:**
Not hazardous for water.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
· **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** UN1790

· **UN proper shipping name**
· **ADR** 1790 HYDROFLUORIC ACID mixture
· **IMDG, IATA** HYDROFLUORIC ACID mixture

· **Transport hazard class(es)**

· **ADR**

· **Class** 8 Corrosive substances.

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Trade name: Ultradent™ Porcelain Etch

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· **Label**	8+6.1
· **IMDG**	
	
· **Class**	8 Corrosive substances.
· **Label**	8/6.1
· **IATA**	
	
· **Class**	8 Corrosive substances.
· **Label**	8 (6.1)
· **Packing group**	
· **ADR, IMDG, IATA**	II
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Warning: Corrosive substances.
· **Hazard identification number (Kemler code):**	86
· **EMS Number:**	F-A,S-B
· **Segregation groups**	Strong acids
· **Stowage Category**	D
· **Stowage Code**	SW1 Protected from sources of heat. SW2 Clear of living quarters.
· **Handling Code**	H2 Keep as cool as reasonably practicable
· **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**	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 1790 HYDROFLUORIC ACID MIXTURE, 8 (6.1), II

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Trade name: Ultradent™ Porcelain Etch

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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*** *H2 ACUTE TOXIC*
· ***Qualifying quantity (tonnes) for the application of lower-tier requirements*** *50 t*
· ***Qualifying quantity (tonnes) for the application of upper-tier requirements*** *200 t*
· ***REGULATION (EC) No 1907/2006 ANNEX XVII*** *Conditions of restriction: 3*
· ***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***
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H330 Fatal if inhaled.

· ***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
Acute Tox. 2: Acute toxicity - oral – Category 2
Acute Tox. 3: Acute toxicity - oral – Category 3
Acute Tox. 1: Acute toxicity - dermal – Category 1
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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

Printing date 06.03.2020 *Revision: 11.04.2019*

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

· **Product identifier**

· **Trade name: OpalDam™**

· **Article number:** 32103
· **Index number:** SDS 2-001.13
· **Relevant identified uses of the substance or mixture and uses advised against**
Professional Light Cure Resin Barrier
· **Application of the substance / the mixture** Professional Light Cure Resin Barrier

· **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@utradent.com

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

· **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**

GHS07

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:**
Diurethane Dimethacrylate
Amine Methacrylate
· **Hazard statements**
H317 May cause an allergic skin reaction.

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Trade name: OpalDam™

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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.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
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: 72869-86-4 EINECS: 276-957-5	Diurethane Dimethacrylate Skin Sens. 1, H317	>50-≤100%
CAS: 112926-00-8 EC number: 601-214-2	Synthetic Amorphous Silica Acute Tox. 3, H331	>2.5-≤10%
	Amine Methacrylate Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≤2.5%

· **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:**
Seek medical treatment in case of complaints.
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. 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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Trade name: OpalDam™

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5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:** 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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **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:** No special precautions are necessary if used correctly.
· **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:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
See product labelling.
Keep container tightly sealed.
· **Specific end use(s)** Professional Light Cure Resin Barrier

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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **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.
Avoid contact with the eyes.
· **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.

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Trade name: OpalDam™

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· **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:** Goggles recommended during refilling
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Viscous Liquid
Colour:	Yellow tint
· **Odour:**	Acrylic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not applicable (non-aqueous)
· **Change in condition**	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· **Flash point:**	>100 °C
· **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:**	1.11 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.

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Trade name: OpalDam™

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· **Solubility in / Miscibility with water:**	Insoluble.
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **Solvent content:**	
VOC (EC)	0.25-0.5 %
· **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:** No further relevant information available.
· **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:**

ATE (Acute Toxicity Estimates)		
Inhalative	LC50/4 h	>17.3 mg/l (rat)

72869-86-4 Diurethane Dimethacrylate		
Oral	LD50	>5,000 mg/kg (rat)

112926-00-8 Synthetic Amorphous Silica		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.69 mg/l (rat)

Amine Methacrylate		
Oral	LD50	1,550 mg/kg (rat)
	LC50 Fish	19 mg/l (Fish)
Dermal	LD50	2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	96 mg/l (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 (carcinogenity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

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· ***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:***	
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)
Amine Methacrylate	
EC50	*42 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***	
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*

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· **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.
· **UN "Model Regulation":**	not regulated

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
· **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.
H331 Toxic if inhaled.

· **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
Acute Tox. 4: Acute toxicity - oral – Category 4
Acute Tox. 3: Acute toxicity - inhalation – Category 3
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

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

· **Product identifier**

· **Trade name: Peak™ Universal Bond**

· **Article number:** SDS 206-001.13, 71057
· **Relevant identified uses of the substance or mixture and uses advised against** Professional Dental Adhesive
· **Application of the substance / the mixture** Professional Dental Adhesive

· **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 Westhover 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:**
During normal opening times: +1 (801) 553-4862
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**


flame

Flam. Liq. 3 H226 Flammable liquid and vapour.


corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.

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Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** GHS02, GHS05, GHS07
· **Signal word** Danger

· **Hazard-determining components of labelling:**
Methacrylic Acid
2-Hydroxyethyl Methacrylate
Trade Secret
Organophosphine Oxide
· **Hazard statements**
H226 Flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.
· **Precautionary statements**

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P103	Read carefully and follow all instructions.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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.
P310	Immediately call a POISON CENTER/doctor.
P321	Specific treatment (see on this label).
P362+P364	Take off contaminated clothing and wash it before reuse.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/information on ingredients

· **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	>10-≤25%
CAS: 868-77-9 EINECS: 212-782-2	2-Hydroxyethyl Methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	>10-≤25%
CAS: 79-41-4 EINECS: 201-204-4	Methacrylic Acid Acute Tox. 3, H331; Skin Corr. 1A, H314; Eye Dam. 1, H318; Acute Tox. 4, H302; Acute Tox. 4, H312 Specific concentration limit: STOT SE 3; H335: C ≥ 1 %	≥5-≤10%
	Trade Secret Skin Corr. 1A, H314	≥1-<5%

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CAS: 162881-26-7 ELINCS: 423-340-5	Organophosphine Oxide Skin Sens. 1A, H317; Aquatic Chronic 4, H413	≥0.1-<1%
CAS: 56-95-1 EINECS: 200-302-4	Chlorhexidine Diacetate Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Acute Tox. 4, H302	≥0.025-<0.25%
CAS: 128-37-0 EINECS: 204-881-4	Butylated Hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Acute Tox. 4, H302	≥0.025-<0.25%

· ***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. Then consult a doctor.*
· ***After swallowing:*** *Drink plenty of water and provide fresh air. Call for a doctor immediately.*
· ***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*
· ***For safety reasons unsuitable extinguishing agents:*** *Water with full jet*
· ***Special hazards arising from the substance or mixture***
During heating or in case of fire poisonous gases are produced.
· ***Advice for firefighters:***
· ***Protective equipment:***
General: Evacuate all personnel; use protective equipment for fire fighting. Use self-contained breathing apparatus when the product is involved in 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 product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
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.

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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

· **Precautions for safe handling:**
Keep away from heat and direct sunlight.
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.
Keep respiratory protective device available.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
See product labelling.
Keep container tightly sealed.
· **Specific end use(s)** Professional Dental Adhesive

8 Exposure controls/personal protection

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
64-17-5 Ethyl Alcohol	
WEL	Long-term value: 1920 mg/m³, 1000 ppm
79-41-4 Methacrylic Acid	
WEL	Short-term value: 143 mg/m³, 40 ppm Long-term value: 72 mg/m³, 20 ppm
128-37-0 Butylated Hydroxytoluene	
WEL	Long-term value: 10 mg/m³

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

· **Exposure controls**
· **Appropriate engineering controls** No further data; see item 7.
· **Individual protection measures, such as 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.
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.

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· ***Hand protection***

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/face protection***

Tightly sealed goggles

· ***Body protection:*** *Protective work clothing*

9 Physical and chemical properties

· ***Information on basic physical and chemical properties***	
· ***General Information***	
· ***Physical state***	*Fluid*
· ***Colour:***	*Light yellow*
· ***Odour:***	*Acrylic*
· ***Odour threshold:***	*Not determined.*
· ***Melting point/freezing point:***	*Undetermined.*
· ***Boiling point or initial boiling point and boiling range***	*60 °C*
· ***Flammability***	*Flammable.*
· ***Lower and upper explosion limit***	
· ***Lower:***	*3.5 Vol %*
· ***Upper:***	*15 Vol %*
· ***Flash point:***	*24 °C*
· ***Ignition temperature:***	*425 °C*
· ***Decomposition temperature:***	*Not determined.*
· ***pH***	*Not applicable (non-aqueous)*
· ***Viscosity:***	
· ***Kinematic viscosity***	*Not determined.*
· ***Dynamic:***	*Not determined.*
· ***Solubility***	
· ***water:***	*Not miscible or difficult to mix.*
· ***Partition coefficient n-octanol/water (log value)***	*Not determined.*
· ***Vapour pressure at 20 °C:***	*59 hPa*
· ***Density and/or relative density***	
· ***Density at 20 °C:***	*1.1 g/cm³*
· ***Relative density***	*Not determined.*

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· **Vapour density**	Not determined.
· **Other information**	
· **Appearance:**	
· **Form:**	Liquid
· **Important information on protection of health and environment, and on safety.**	
· **Auto-ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· **Solvent content:**	
· **VOC (EC)**	<20.00 %
· **Solids content:**	<15.0 %
· **Change in condition**	
· **Evaporation rate**	Not determined.
· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Flammable liquid and vapour.
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

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:** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known.

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11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity**

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Oral	LD50	17,667 mg/kg
Dermal	LD50	8,333 mg/kg (rabbit)
Inhalative	LC50/4 h	118 mg/l

64-17-5 Ethyl Alcohol		
Oral	LD50	5,600 mg/kg (Guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
	LC50 Fish	>10,000 mg/l (Fish)
Inhalative	LC50/4 h	39 mg/l (mouse)
		20,000 mg/l (rat)

868-77-9 2-Hydroxyethyl Methacrylate		
Oral	LD50	3,275 mg/kg (mouse)
		>5,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>3,000 mg/kg (rabbit)
	LC50(Daphnia magna)	24.1 mg/l (daphnia)

79-41-4 Methacrylic Acid		
Oral	LD50	1,250 mg/kg (mouse)
		1,060 mg/kg (rat)
		1,200 mg/kg (rabbit)
	LC50 Fish	86 mg/l (Fish)
Dermal	LD50	1,000 mg/kg (Guinea pig)
		500 mg/kg (rabbit)
Inhalative	LC50/4 h	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)

56-95-1 Chlorhexidine Diacetate		
Oral	LD50	2,000 mg/kg (mouse)
		1,180 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

128-37-0 Butylated Hydroxytoluene		
Oral	LD50	10,700 mg/kg (Guinea pig)
		1,040 mg/kg (mouse)
		890 mg/kg (rat)
	LC50 Fish	5.3 mg/l (Fish)

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Dermal	LD50	>2,000 mg/kg (rat)

· **Skin corrosion/irritation** Causes severe skin burns and eye damage.
· **Serious eye damage/irritation** Causes serious eye damage.
· **Respiratory or skin sensitisation** May cause an allergic skin reaction.
· **STOT-single exposure** May cause respiratory irritation.
· **Information on other hazards**

· **Endocrine disrupting properties**		
128-37-0	Butylated Hydroxytoluene	List II

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
64-17-5 Ethyl Alcohol	
Algae Toxicity	1,000 mg/l (Algae)
868-77-9 2-Hydroxyethyl Methacrylate	
EC50	345 mg/kg (Algae)
79-41-4 Methacrylic Acid	
EC50	17,000 mg/kg (Algae) <180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
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)
128-37-0 Butylated Hydroxytoluene	
Aqua toxicity (static)	0.48 mg/l (daphnia) (Toxicity to aquatic invertebrates)

· **Persistence and degradability** No further relevant information available.
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
· **Other adverse effects**
· **Remark:** Harmful to fish
· **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.
Harmful to aquatic organisms

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Dispose of contents/container in accordance with international, federal, state, and local regulations.

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

14 Transport information

· ***UN number or ID number***
· ***ADR, IMDG, IATA*** *UN2924*

· ***UN proper shipping name***
· ***ADR*** *2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHACRYLIC ACID, STABILIZED, Ethyl Alcohol)*
· ***IMDG, IATA*** *FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHACRYLIC ACID, STABILIZED, Ethyl Alcohol)*

· ***Transport hazard class(es)***

· ***ADR***

· ***Class*** *3 Flammable liquids.*
· ***Label*** *3+8*

· ***IMDG***

· ***Class*** *3 Flammable liquids.*
· ***Label*** *3/8*

· ***IATA***

· ***Class*** *3 Flammable liquids.*
· ***Label*** *3 (8)*

· ***Packing group***
· ***ADR, IMDG, IATA*** *III*

· ***Environmental hazards:*** *Not applicable.*

· ***Special precautions for user*** *Warning: Flammable liquids.*
· ***Hazard identification number (Kemler code):*** *38*
· ***EMS Number:*** *F-E,S-C*
· ***Stowage Category*** *A*
· ***Stowage Code*** *SW2 Clear of living quarters.*

· ***Maritime transport in bulk according to IMO instruments*** *Not applicable.*

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· ***Transport/Additional information:***

· ***ADR***	
· ***Limited quantities (LQ)***	*5L*
· ***Excepted quantities (EQ)***	*Code: E1* *Maximum net quantity per inner packaging: 30 ml* *Maximum net quantity per outer packaging: 1000 ml*
· ***Transport category***	*3*
· ***Tunnel restriction code***	*D/E*
· ***IMDG***	
· ***Limited quantities (LQ)***	*5L*
· ***Excepted quantities (EQ)***	*Code: E1* *Maximum net quantity per inner packaging: 30 ml* *Maximum net quantity per outer packaging: 1000 ml*
· ***UN "Model Regulation":***	*UN 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHACRYLIC ACID, STABILIZED, ETHYL ALCOHOL), 3 (8), III*

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*
· ***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 from Section 3***
H225 Highly flammable liquid and vapour.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H413 May cause long lasting harmful effects to aquatic life.

· ***Department issuing SDS:*** *Environmental, Health, and Safety*
· ***Contact:*** *Customer Service*

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Trade name: Peak™ Universal Bond

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· ***Abbreviations and acronyms:***
ADR: Accord relatif au transport international 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
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 3: Acute toxicity – Category 3
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
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4
· **** Data compared to the previous version altered.***

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

Printing date 10.09.2019 *Revision: 12.04.2019*

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

· **Product identifier**

· **Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple**

· **Article number:** 10065, 72296, 76377, 76387, 94608, 94613, 94617, 94621, 94625, 94630, 94636, 94705
· **Index number:** SDS 55-001.11
· **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Restorative Material
· **Application of the substance / the mixture** Professional Dental Restorative Material

· **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@utradent.com

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

· **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**

GHS07

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
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
2-Hydroxyethyl Methacrylate

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

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Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple

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Diurethane Dimethacrylate
Amine Methacrylate
Organophosphine Oxide

· **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

· **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.
P280	Wear protective gloves / eye protection / face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
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	<30%
CAS: 868-77-9 EINECS: 212-782-2	2-Hydroxyethyl Methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	<20%
CAS: 72869-86-4 EINECS: 276-957-5	Diurethane Dimethacrylate Skin Sens. 1, H317	<20%
	Amine Methacrylate Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	<1%
CAS: 162881-26-7 ELINCS: 423-340-5	Organophosphine Oxide Skin Sens. 1, H317; Aquatic Chronic 4, H413	<1%
CAS: 10163-15-2 EINECS: 233-433-0	Sodium Monofluorophosphate Acute Tox. 4, H302	0.3%

· **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:** This product is a viscous gel, therefore chance of inhalation is extremely low.

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Safety data sheet
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Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple

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· **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 swallowed in large quantities seek medical attention.
· **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:**
Water spray
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:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

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:**
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.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· **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:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
See product labelling.

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Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple

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Store in a cool place.
Store in the dark.
Protect from exposure to the light.
Keep container tightly sealed.
· ***Specific end use(s)*** *Professional Dental Restorative Material*

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:***
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· ***Additional information:*** *The lists valid during the making were used as basis.*

· ***Exposure controls***
· ***Personal protective equipment:***
· ***General protective and hygienic measures:***
Do not eat, drink, smoke or sniff while working.
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

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*

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Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Gel
Colour:	According to product specification
· **Odour:**	Acrylic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not applicable (non-aqueous)
· **Change in condition**	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gas):**	Not applicable.
· **Ignition temperature:**	255 °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:**	1.8-2 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **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:**	
VOC (EC)	0.00 %
Solids content:	<80 %
· **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.

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Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple

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· **Conditions to avoid:**
Light
Flames
Ignition sources
Heat
· **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)
Dermal	LD50	>2,000 mg/kg (mouse)
868-77-9 2-Hydroxyethyl Methacrylate		
Oral	LD50	3,275 mg/kg (mouse)
		>5,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>3,000 mg/kg (rabbit)
	LC50(Daphnia magna)	24.1 mg/l (daphnia)
72869-86-4 Diurethane Dimethacrylate		
Oral	LD50	>5,000 mg/kg (rat)
Amine Methacrylate		
Oral	LD50	1,550 mg/kg (rat)
	LC50 Fish	19 mg/l (Fish)
Dermal	LD50	2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	96 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**
Causes skin irritation.
· **Serious eye damage/irritation**
Causes serious eye irritation.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **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.

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Printing date 10.09.2019 *Revision: 12.04.2019*

Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple

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· ***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)*
868-77-9 2-Hydroxyethyl Methacrylate	
EC50	*345 mg/l (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)
Amine Methacrylate	
EC50	*42 mg/l (Algae)*
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***	
HP13	*Sensitising*

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according to 1907/2006/EC, Article 31

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Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple

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· **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.
· **UN "Model Regulation":**	not regulated

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
· **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

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

Printing date 10.09.2019 *Revision: 12.04.2019*

Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple

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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
Acute Tox. 4: Acute toxicity – 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

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

Printing date 16.01.2020 *Revision: 03.12.2019*

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

· **Product identifier**

· **Trade name: Silane**

· **Article number:** 10325
· **Index number:** SDS 5-001.15
· **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Bonding Agent
· **Application of the substance / the mixture** Professional Dental Bonding 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@utradent.com

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

· **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**

GHS02 flame

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

GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.
STOT SE 3 H336 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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Safety data sheet
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Printing date 16.01.2020 Revision: 03.12.2019

Trade name: Silane

(Contd. of page 1)

· **Signal word** Danger

· **Hazard-determining components of labelling:**
Isopropyl Alcohol
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 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/bond container and receiving equipment.
P241	Use explosion-proof electrical/ventilating/lighting equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
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.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ 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.
P312	Call a POISON CENTER/doctor if you feel unwell.
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: 67-63-0 EINECS: 200-661-7	Isopropyl Alcohol Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	>50-≤100%
CAS: 2530-85-0 EINECS: 219-785-8	Silane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	>2.5-≤10%

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

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

Printing date 16.01.2020 *Revision: 03.12.2019*

Trade name: Silane

(Contd. of page 2)

4 First aid measures

· ***Description of first aid measures***
· ***General information:*** *Immediately remove any clothing soiled by the product.*
· ***After inhalation:***
Move to fresh air. If breathing is difficult, give oxygen. Perform artificial respiration if breathing has stopped. Get medical attention immediately.
· ***After skin contact:***
Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if symptoms occur. Take off immediately all contaminated clothing. Rinse skin with water [or shower].
· ***After eye contact:***
Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
· ***After swallowing:***
Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly.
· ***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:***
Carbon dioxide or dry powder. Water in large amounts. Alcohol resistant foam. Use fire-extinguishing media appropriate for surrounding materials.
· ***Special hazards arising from the substance or mixture***
Heat may cause the containers to explode. Vapors may travel considerable distance to a source of ignition and flash back. Vapors may cause a flash fire or ignite explosively. Prevent buildup of vapors or gases to explosive concentrations.
· ***Advice for firefighters:***
· ***Protective equipment:***
Use water spray to keep fire-exposed containers cool. Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.
· ***Additional information***
Use water spray to keep fire-exposed containers cool. Water may be ineffective in fighting the fire. Fight fire from a protected location. Move containers from fire area if you can do so without risk.

6 Accidental release measures

· ***Personal precautions, protective equipment and emergency procedures***
Use personal protective equipment. Keep unauthorized personnel away. Ventilate closed spaces before entering them. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep upwind.

(Contd. on page 4)

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

Printing date 16.01.2020 Revision: 03.12.2019

Trade name: Silane

(Contd. of page 3)

· **Environmental precautions:**
Do not contaminate water sources or sewer. Prevent further leakage or spillage if safe to do so.
· **Methods and material for containment and cleaning up:**
All equipment used when handling the product must be grounded. Absorb spill with vermiculite or other inert material, then place in a container for chemical waste. Dike far ahead of larger spill for later recovery and disposal. In case of leakage, eliminate all ignition sources.
Dike for later disposal. Prevent entry into waterways, sewer, basements or confined areas. Stop the flow of material, if this is without risk.
· **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:**
Flammable/combustible - Keep away from oxidizers, heat and flames.
Avoid contact with skin and eyes. Avoid breathing mists or vapors. Use only with adequate ventilation. Wash hands thoroughly after handling.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground and bond container and receiving equipment. Take precautionary measures against static discharges.
· **Information about fire - and explosion protection:**
Fumes can combine with air to form an explosive mixture.
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:**
Provide ventilation for receptacles.
Store in a cool location.
· **Information about storage in one common storage facility:** Store away from oxidising agents.
· **Further information about storage conditions:**
Store receptacle in a well ventilated area.
Store in a cool place.
Protect from contamination.
Protect from heat
See product labelling.
Keep container tightly sealed.
Store in cool, dry conditions in well - sealed receptacles.
· **Specific end use(s)** Professional Dental Bonding Agent

8 Exposure controls/personal protection

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

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Trade name: Silane

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· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
67-63-0 Isopropyl Alcohol	
WEL (Great Britain)	Short-term value: 1250 mg/m³, 500 ppm Long-term value: 999 mg/m³, 400 ppm

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

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Good general ventilation (typically 10 air changes per hour) should be used.
Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If exposure limits have not been established, maintain airborne levels to an acceptable level.
Use personal protective equipment as required.
Practice good housekeeping.
Use explosion-proof ventilation equipment.
Discard contaminated footwear that cannot be cleaned.
Routinely wash work clothing and protective equipment to remove contaminants.
Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking.
When using do not smoke.
Special rooms for washing, showering and changing are required.
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.
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

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.

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· **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:	Colourless
· **Odour:**	Alcohol-like
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	5-8
· **Change in condition**	
Melting point/freezing point:	-89 °C
Initial boiling point and boiling range:	82 °C
· **Flash point:**	17 °C
· **Flammability (solid, gas):**	Not applicable.
· **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:	Not determined.
Upper:	Not determined.
· **Vapour pressure:**	Not determined.
· **Density at 20 °C:**	<1 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with water:**	Fully miscible.
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	<95 %
Water:	<5 %
VOC (EC)	<95%

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· **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:** Danger of explosion.
· **Conditions to avoid:**
Sparks
Flames
Ignition sources
Heat
· **Incompatible materials:**
Aldehydes
Alkalis
Amines
Isocyanates
Strong oxidizing agents
· **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:**

67-63-0 Isopropyl Alcohol

Oral	LD50	3,600 mg/kg (mouse)
		4,710 mg/kg (rat)
		5,030 mg/kg (rabbit)
	LC50 Fish	9,640 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>12,800 mg/kg (rabbit)
Inhalative	LC50/4 h	26.5 mg/l (mouse)
		25.52 mg/l (rat)
	LC50 Crustacean	278 mg/l (Crustacean)
	LC50(Daphnia magna)	>1,000 mg/l (daphnia) (Toxicity to aquatic invertebrates)

· **Primary irritant effect:**
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation**
Causes serious eye irritation.
· **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**
May cause drowsiness or dizziness.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
67-63-0 Isopropyl Alcohol	
EC50	>1,000 mg/kg (Algae)
EC50	>100 mg/l (Fish)

· **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**	
HP3	Flammable
HP4	Irritant - skin irritation and eye damage
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

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

14 Transport information

· **UN-Number**	
· **ADR, IMDG, IATA**	UN1993
· **UN proper shipping name**	
· **ADR**	1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL))
· **IMDG, IATA**	FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL))

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· **Transport hazard class(es)**

· **ADR, IMDG, IATA**

· **Class**	3 Flammable liquids.
· **Label**	3
· **Packing group**	
· **ADR, IMDG, IATA**	II
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Warning: Flammable liquids.
· **Danger code (Kemler):**	33
· **EMS Number:**	F-E,S-E
· **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 1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL 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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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.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.

· ***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 Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Safety data sheet
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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 Westhover 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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· **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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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	
WEL (Great Britain)	*Short-term value: 2 mg/m³* *Long-term value: 1 mg/m³*

· ***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/cm³
· **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, hyrogen gas
· **Additional information:**
Reacts with bases to form phosphate salts and is corrosive (especially when hot) to many metals and alloys. Liberates exposive 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

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· **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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· **UN proper shipping name**	
· **ADR**	1805 PHOSPHORIC ACID, SOLUTION mixture
· **IMDG, IATA**	PHOSPHORIC ACID, SOLUTION mixture
· **Transport hazard class(es)**	
· **ADR, IMDG, IATA**	
· **Class**	8 Corrosive substances.
· **Label**	8
· **Packing group**	
· **ADR, IMDG, IATA**	III
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Warning: Corrosive substances.
· **Hazard identification number (Kemler code):**	80
· **EMS Number:**	F-A,S-B
· **Segregation groups**	Acids
· **Stowage Category**	A
· **Segregation Code**	SG36 Stow "separated from" SGG18-alkalis. SG49 Stow "separated from" SGG6-cyanides
· **Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **Transport category**	3
· **Tunnel restriction code**	E
· **IMDG**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **UN "Model Regulation":**	UN 1805 PHOSPHORIC ACID, SOLUTION MIXTURE, 8, III

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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· ***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