

Printing date 20.04.2015 Version number 9 Revision: 18.02.2015

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

· 1.1 Product identifier

· Trade name: Total Etch

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

No further relevant information available.

· Application of the substance / the mixture Etching Gel

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Ivoclar Vivadent AG Bendererstrasse 2 FL-9494 Schaan

FÜRSTENTUM LIECHTENSTEIN

Tel: +423 235 35 35 Fax: +423 235 33 60

· Further information obtainable from:

Regulatory Affairs sds@ivoclarvivadent.com

• 1.4 Emergency telephone number: +423/235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

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

Eye Dam. 1 H318 Causes serious eye damage.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



- · Signal word Danger
- · Hazard-determining components of labelling: phosphoric acid

· Hazard statements

H314 Causes severe skin burns and eye damage.

· Precautionary statements

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

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

Immediately call a POISON CENTER/doctor.

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

· Additional information:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

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- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

•	Dangerous	components:
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CAS: 7664-38-2 phosphoric acid EINECS: 231-633-2

Skin Corr. 1B, H314

25-50%

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: Immediately remove any clothing soiled by the product.
- · After inhalation:

Supply fresh air; consult doctor in case of complaints.

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

· After skin contact:

Immediately rinse with water.

If skin irritation continues, consult a doctor.

- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing:

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; call for medical help immediately.

- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

The product is not flammable.

Use fire extinguishing methods suitable to surrounding conditions.

· 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Dilute with plenty water.

Use neutralising agent.

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Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item 13.

· 6.4 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.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling No special precautions are necessary if used correctly.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Keep container tightly sealed.

Protect from heat and direct sunlight.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

7664-38-2 phosphoric acid

WEL Short-term value: 2 mg/m³ Long-term value: 1 mg/m³

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Usual hygienic measures for dental practice.

Avoid contact with the eyes and skin.

Immediately remove all soiled and contaminated clothing

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

- · Respiratory protection: Not required.
- · Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

Butyl rubber, BR

Fluorocarbon rubber (Viton)

Nitrile rubber, NBR

Natural rubber, NR

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Chloroprene rubber, CR

The selection of the 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 break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

9.1 Information on basic physical and chemical properties			
· General Information			
Appearance: Form:	Viscous		
Colour:	Viscous Blue		
Odour:	Odourless		
Odour threshold:	Not determined.		
pH-value at 20 °C:	< 1		
Change in condition			
Melting point/Melting range:	Undetermined.		
Boiling point/Boiling range:	Undetermined.		
Flash point:	Not applicable.		
Flammability (solid, gaseous):	Not applicable.		
Ignition temperature:			
Decomposition temperature:	Not determined.		
Self-igniting:	Product is not selfigniting.		
Danger of explosion:	Product does not present an explosion hazard.		
Explosion limits:			
Lower:	Not determined.		
Upper:	Not determined.		
Vapour pressure:	Not determined.		
Density at 20 °C:	$1.29 \ g/cm^3$		
Relative density	Not determined.		
Vapour density	Not determined.		
Evaporation rate	Not determined.		
Solubility in / Miscibility with			
water:	Soluble.		
Partition coefficient (n-octanol/wat	er). Not determined		

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Kinematic: Not determined.

• 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values relevant for classification:

7664-38-2 phosphoric acid

Oral LD50 1530 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: Caustic effect on skin and mucous membranes.
- · on the eye: Strong caustic effect.
- · Sensitisation: No sensitising effects known.
- · Additional toxicological information:

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 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.

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

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SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

· European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

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

14.1 UN-Number ADR, IMDG, IATA	UN1805
14.2 UN proper shipping name ADR IMDG, IATA	1805 PHOSPHORIC ACID, SOLUTION PHOSPHORIC ACID, SOLUTION
14.3 Transport hazard class(es)	
ADR	
15 34 S	
Class	8 (C1) Corrosive substances.
Label	8
No. of the second secon	
Class	8 Corrosive substances.
Label	8
14.4 Packing group ADR, IMDG, IATA	III
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Corrosive substances.
Danger code (Kemler):	80 E A C B
EMS Number:	F-A,S-B
14.7 Transport in bulk according to Anno MARPOL73/78 and the IBC Code	ex II of Not applicable.
Transport/Additional information:	
Limited quantities (LQ)	5L

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· 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
\cdot Excepted quantities (\widetilde{EQ})	Code: E1
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN1805, PHOSPHORIC ACID, SOLUTION, 8, III

SECTION 15: Regulatory information

- $\cdot 15.1\ Safety,\ health\ and\ environmental\ regulations/legislation\ specific\ for\ the\ substance\ or\ mixture$
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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

H314 Causes severe skin burns and eye damage.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

* * Data compared to the previous version altered.

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