

Printing date 18.10.2019 Version number 10 Revision: 26.09.2019

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- · Trade name: Total Etch
- · 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
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent AG Bendererstrasse 2

9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN

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

Importer:

Ivoclar Vivadent Pty. Ltd.

1- 5 Overseas Drive

Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· Further information obtainable from:

Regulatory Affairs

sds@ivoclarvivadent.com

· Emergency telephone number: 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

· Classification of the substance or mixture

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

Eye Dam. 1 H318 Causes serious eye damage.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS05

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

phosphoric acid

· Hazard statements

Causes severe skin burns and eye damage.

· Precautionary statements

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

IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

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

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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.

· 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.

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

3 Composition and Information on Ingredients

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

CAS: 7664-38-2 phosphoric acid

Skin Corr. 1B, H314; Acute Tox. 4, H302

25-50%

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

4 First Aid Measures

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

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

Supply fresh air; consult doctor in case of complaints.

· 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.

- · 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 Fire Fighting Measures

- · Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- $\cdot \textit{Special hazards arising from the substance or mixture}$

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

- · Advice for firefighters
- · Protective equipment: No special measures required.
- · Additional information See Section 14 for Hazchem Code.

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6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

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

Dilute with plenty water.

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

Only adequately trained personnel should handle this product.

For use in dentistry only.

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: 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.

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

8 Exposure controls and 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:

CAS: 7664-38-2 phosphoric acid

NES | Short-term value: 3 mg/m³

Long-term value: 1 mg/m³

WES Short-term value: 3 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:

Usual hygienic measures for dental practice and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

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Wash hands before breaks and at the end of work.

Do not inhale gases / fumes / aerosols.

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

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Butyl rubber, BR

Fluorocarbon rubber (Viton)

Nitrile rubber, NBR

Natural rubber, NR

Chloroprene rubber, CR

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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

Tightly sealed goggles (EN 166)

| Information on basic physical and chemic General Information | ical properties | |
|--|---|--|
| Appearance: | | |
| Form: | Viscous | |
| 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: | Undetermined. | |
| 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. | |

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|---|--|-----------------|
| · Explosion limits: | | |
| Lower: | Not determined. | |
| Upper: | Not determined. | |
| · Vapour pressure: | Not determined. | |
| · Density at 20 °C: | 1.29 g/cm³ | |
| Relative density | Not determined. | |
| · Vapour density | Not determined. | |
| Evaporation rate | Not determined. | |
| · Solubility in / Miscibility with | | |
| water: | Soluble. | |
| Partition coefficient: n-octanol/water: | Not determined. | |
| · Viscosity: | | |
| Dynamic: | Not determined. | |
| Kinematic: | Not determined. | |
| · Other information | No further relevant information available. | |

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under normal handling and storage conditions.
- 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: None under normal conditions of storage and use.

11 Toxicological Information

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

CAS: 7664-38-2 phosphoric acid

Oral LD50 1530 mg/kg (rat)

- · Skin corrosion/irritation Caustic effect on skin and mucous membranes.
- · Serious eye damage/irritation

Strong caustic effect.

Strong irritant with the danger of severe eye injury.

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.

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.

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- · 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.

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

| UN-Number ADG, IMDG, IATA | UN1805 |
|--|---|
| UN proper shipping name ADG IMDG, IATA | 1805 PHOSPHORIC ACID, SOLUTION PHOSPHORIC ACID, SOLUTION |
| Transport hazard class(es) | |
| ADG | |
| 8 | |
| Class | 8 (C1) Corrosive substances. |
| Label | 8 |
| IMDG, IATA | |
| Class | 8 Corrosive substances. |
| Label | 8 |
| Packing group ADG, IMDG, IATA | III |

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|--|---|
| Environmental hazards: | |
| Marine pollutant: | No |
| Special precautions for user | Warning: Corrosive substances. |
| Danger code (Kemler): | 80 |
| Hazchem or Emergency Action Code: | 2R |
| EMS Number: | F- A , S - B |
| Stowage Category | A |
| Transport in bulk according to Annex II of M | Marpol |
| and the IBC Code | Not applicable. |
| Transport/Additional information: | |
| ADG | |
| Limited quantities (LQ) | 5L |
| Excepted quantities (\widetilde{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 (\widetilde{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, 8, III |

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Chemical Substances

CAS: 7664-38-2 phosphoric acid

· Standard for the Uniform Scheduling of Medicines and Poisons

CAS: 7664-38-2 phosphoric acid

S5, S6

· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



- GHS05
- · Signal word Danger
- · Hazard-determining components of labelling:

phosphoric acid

· Hazard statements

Causes severe skin burns and eye damage.

· Precautionary statements

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

IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

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

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

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

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

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.

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

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity - Category 4

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

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

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