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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 preparation Etching Gel
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

USA

Tel. +1 800 533 6825

Fax +1 716 691 2285

Ivoclar Vivadent Inc.

1-6600 Dixie Road

Mississauga, Ontario

L5T 2Y2 Canada

Phone: +1 905 670 8499 *Fax:* +1 905 670 3102

· Information department: Quality Assurance / Regulatory Affairs

Emergency telephone number:

24 Hour Emergency Assistance:

Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

General MSDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Corrosive

Causes burns.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- · Label elements
- · Labelling according to EU guidelines:

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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· Code letter and hazard designation of product:



Corrosive

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· Hazard-determining components of labeling: phosphoric acid

· Risk phrases:

Causes burns.

· Safety phrases:

When using do not eat or drink.

Do not breathe spray.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). This material and its container must be disposed of as hazardous waste.

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 3 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



3 Health = 3

Fire=0

REACTIVITY 0 Reactivity = 0

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

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous o	components:	
7664-38-2	phosphoric acid	25-50%
25322-68-3	Polyethylene glycol	2.5-<10%

4 First-aid measures

- · 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; immediately call for medical help.

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

No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

The product is not flammable.

Use fire fighting measures that suit the environment.

· 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.

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.

Use neutralizing agent.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

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 protection against explosions and fires: 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 receptacle tightly sealed.

Protect from heat and direct sunlight.

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

8 Exposure controls/personal protection

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

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· Control parameters

• Components with limit values that require monitoring at the workplace:

7664-38-2 phosphoric acid

 $PEL \quad 1 \, mg/m^3$

REL Short-term value: 3 mg/m³ Long-term value: 1 mg/m³

TLV Short-term value: 3 mg/m³ Long-term value: 1 mg/m³

25322-68-3 Polyethylene glycol

WEEL 10 mg/m³

(H); MW>200

- · Additional information: The lists that were valid during the creation were used as basis.
- · 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.

- · Breathing equipment: 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

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

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Information on basic physical and o	chemical properties
General Information	
Appearance:	
Form:	Viscous
Color:	Blue
Odor:	Odorless
Odour threshold:	Not determined.
pH-value at 20 °C (68 °F):	< 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.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density at 20 °C (68 °F):	1.29 g/cm³ (10.765 lbs/gal)
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.
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.
- $\cdot \textbf{Incompatible materials:} \ No \ further \ relevant \ information \ available.$
- · Hazardous decomposition products: None under normal conditions of storage and use.

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11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are 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.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Corrosive

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

- · Carcinogenic categories
- · NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- $\cdot \textbf{\it Bioaccumulative potential} \ No \ further \ relevant \ information \ available.$
- · Mobility in soil No further relevant information available.
- · Additional ecological information:

Water hazard class 1 (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 bodies of water or drainage ditch undiluted or unneutralized.

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 of together with household garbage. Do not allow product to reach sewage system. (Contd. on page 7)

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

UN-Number DOT, ADR, IMDG, IATA	UN1805
UN proper shipping name DOT, IMDG, IATA ADR	PHOSPHORIC ACID, SOLUTION 1805 PHOSPHORIC ACID, SOLUTION
Transport hazard class(es)	
DOT ₹	
Class Label	8 Corrosive substances. 8
ADR V	
Class Label	8 (C1) Corrosive substances 8
IMDG, IATA	
Class Label	8 Corrosive substances. 8
Packing group DOT, ADR, IMDG, IATA	III
Environmental hazards: Marine pollutant:	No
Special precautions for user Danger code (Kemler):	Warning: Corrosive substances 80
EMS Number: Segregation groups	F-A,S-B Acids

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15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara
- · Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

7664-38-2 phosphoric acid

· TSCA (Toxic Substances Control Act):

7732-18-5 water, distilled, conductivity or of similar purity

7664-38-2 phosphoric acid

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Product related hazard informations:

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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· Hazard symbols:



Corrosive

- · Hazard-determining components of labeling: phosphoric acid
- · Risk phrases:

Causes burns.

· Safety phrases:

When using do not eat or drink.

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Do not breathe spray.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). This material and its container must be disposed of as hazardous waste.

- · National regulations:
- · Other regulations, limitations and prohibitive regulations

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

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· 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.

USA