

SAFETY DATA SHEETS

This SDS packet was issued with item:

077092604

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077092612 079881300

MATERIAL SAFETY DATA SHEET

PRODUCT: Enamel Prep Etchant

PRODUCT CODE: 0004017

PRODUCT USE: FOR PROFESSIONAL DENTAL USE ONLY

SECTION 1 - MANUFACTURER/SUPPLIER

=====

Manufacturer/ Supplier
 IVOCLAR NORTH AMERICA
 Vivadent
 175 Pineview Drive
 Amherst, NY 14228

EMERGENCY PHONE: (716) 691-0010

n.av.=not available
 n.ap.=not applicable
 (C)=degrees Celsius

SECTION 2 - INGREDIENTS

=====

PEL & TLV (mg/m3)

COMPONENTS	% RANGE	CAS #	PEL	TLV	LD50/LC50 *TDL _o
Phosphoric Acid	15-40	7664-38-2	1.0	1.0	n.av.

SECTION 3 - HEALTH HAZARDS

=====

PRIMARY ROUTE(S) OF ENTRY: Ingestion Eyes Skin

SYMPTOMS OF ACUTE EXPOSURE:

Irritation to mucous membranes and skin

SYMPTOMS OF CHRONIC EXPOSURE:

Respiratory irritation to mist or vapor

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: None known

CARCINOGEN, OR POTENTIAL CARCINOGEN: None
 NTP: No IARC: No OSHA REG. No

SECTION 4 - FIRST AID MEASURES

=====

INHALATION: Remove to fresh air, seek medical attention if necessary

INGESTION: Drink water and milk, seek medical attention

EYES: Flush with water for 20 minutes, seek medical attention

SKIN: Wash affected area with soap & water

ADAMS, GEORGE A
 STE 114
 4515 HARDING RD 114
 NASHVILLE, TN 37205-2180

=== MSDS TRACKING INFORMATION ===
 MID: 1055114 ENAMEL PREP BLUE GEL 5M
 PID: 9459815 CUST: 0306520-001
 IMG: I:55114 1 PAGE: 1 of 2
PACKET: 35409-2013

PRODUCT: Enamel Prep Etchant

PRODUCT CODE: 0004017

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SECTION 5 - PHYSICAL/CHEMICAL CHARACTERISTICS
=====

BOILING POINT (C): n.av. MELTING POINT (C): n.av. pH: n.ap.

VAPOR PRESSURE (mm HG): n.av. VAPOR DENSITY (air=1): n.ap.

SPECIFIC GRAVITY (H2O=1, g/cm3): 1.22 g/cm ODOR THRESHOLD (ppm): n.av.

APPEARANCE AND ODOR: Clear or Blue Liquid

SECTION 6 - FIRE OR EXPLOSION DATA
=====

FLASH POINT (C): n.av.

AUTOIGNITION TEMPERATURE (C): n.av.

FLAMMABLE LIMITS % IN AIR, UPPER: n.av.
LOWER: n.av.

EXTINGUISHER MEDIA: Use dry chemical or CO2 extinguisher

OTHER FIRE AND EXPLOSION

HAZARDS: None

SECTION 7 - REACTIVITY DATA
=====

CHEMICAL STABILITY: yes IF NO, UNDER WHAT CONDITIONS:
n.av.

INCOMPATIBILITY WITH OTHER SUBSTANCES: yes
IF SO, WHICH ONES?: Corrosive to metals

REACTIVITY, AND UNDER WHICH CONDITIONS:
Corrosive

SECTION 8 - PREVENTIVE MEASURES
=====

PROTECTIVE CLOTHING

EYES: Safety glasses GLOVES: Impervious neoprene gloves

RESPIRATORY PROTECTION: Dust mask

VENTILATION: Use local exhaust ventilation.

LEAK AND SPILL PROCEDURE: Contain with inert absorbant and collect for incineration

WASTE DISPOSAL METHODS: Dispose according to local regulations

STORAGE: Store in a dry, cool, place

OTHER PREVENTIVE MEASURES: Enamel prep is corrosive

SECTION 9 - PREPARATION DATA
=====

RESEARCH AND DEVELOPMENT (716) 691-0010

PREPARED BY: Gary L. Severance

DATE: 07/01/90

ADAMS, GEORGE A
STE 114
4515 HARDING RD 114
NASHVILLE, TN 37205-2180

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PID: 9459815 CUST: 0306520-001
IMG: I:55114 2 PAGE: 2 of 2
PACKET: 35409-2013

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
FL-9494 Schaan
FÜRSTENTUM LIECHTENSTEIN*
-
- Tel: +423 235 35 35
Fax: +423 235 33 60*
- **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 SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182*

2 Hazard(s) identification

- **Classification of the substance or mixture**
*Skin Corr. 1A 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 labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS05

- **Signal word** *Danger*
- **Hazard-determining components of labeling:**
phosphoric acid
- **Hazard statements**
Causes severe skin burns and eye damage.
- **Precautionary statements**
*Wear protective gloves/protective clothing/eye protection/face protection.
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.
If swallowed: Rinse mouth. Do NOT induce vomiting.*

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Additional information:

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

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

Health = 3
Fire = 0
Reactivity = 2

HMIS-ratings (scale 0 - 4)

HEALTH 3 Health = 3
FIRE 0 Fire = 0
REACTIVITY 2 Reactivity = 2

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 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.

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.

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- 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.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

7664-38-2 phosphoric acid

PEL	Long-term value: 1 mg/m ³
REL	Short-term value: 3 mg/m ³ Long-term value: 1 mg/m ³
TLV	Short-term value: 3 mg/m ³ Long-term value: 1 mg/m ³

25322-68-3 Polyethylene glycol

WEEL	Long-term value: 10 mg/m ³ (H); MW>200
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· **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

9 Physical and chemical properties

· **Information on basic physical and 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.

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· 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/cm ³ (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/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 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.

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- **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.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

7631-86-9 | silicon dioxide, chemically prepared

3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

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:**

- **Bioaccumulative potential:** No further relevant information available.

- **Mobility in soil:** No further relevant information available.

- **Additional ecological information:**

- **General notes:**

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.

- **Uncleaned packagings:**

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

14 Transport information

- **UN-Number**

- **DOT, ADR, IMDG, IATA**

UN1805

- **UN proper shipping name**

- **DOT, IMDG, IATA**

PHOSPHORIC ACID, SOLUTION

- **ADR**

1805 PHOSPHORIC ACID, SOLUTION

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- **Transport hazard class(es)**

- **DOT**



- **Class** 8 Corrosive substances
- **Label** 8

- **ADR**



- **Class** 8 (C1) Corrosive substances
- **Label** 8

- **IMDG, IATA**



- **Class** 8 Corrosive substances
- **Label** 8

- **Packing group** III
- **DOT, ADR, IMDG, IATA** III

- **Environmental hazards:**
- **Marine pollutant:** No

- **Special precautions for user** Warning: Corrosive substances
- **Danger code (Kemler):** 80
- **EMS Number:** F-A,S-B

- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

- **Transport/Additional information:**

- **ADR**
- **Excepted quantities (EQ)** Code: E1
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 1000 ml

- **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":** UN1805, Phosphoric acid solution, 8, III

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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.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



GHS05

· Signal word *Danger*

· Hazard-determining components of labeling:

phosphoric acid

· Hazard statements

Causes severe skin burns and eye damage.

· Precautionary statements

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

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.

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If swallowed: Rinse mouth. Do NOT induce vomiting.

· **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.

· **Date of preparation / last revision** 04/20/2015 / 8

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

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

· *** Data compared to the previous version altered.**

US