

Printing date 09/22/2016 Version number 3 Reviewed on 09/21/2016

1 Identification

- · Product identifier
- · Trade name: Monobond Etch & Prime
- · Application of the substance / the mixture Ceramic primer
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

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USA

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Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada

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- · 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 identification

· Classification of the substance or mixture

Flammable Liquids - Category 3	H226	Flammable liquid and vapour.
Acute Toxicity (Oral) - Category 4	H302	Harmful if swallowed.
Skin Corrosion - Category 1A	H314	Causes severe skin burns and eye damage.
Serious Eye Damage - Category 1	H318	Causes serious eye damage.
Skin Sensitizer - Category 1	H317	May cause an allergic skin reaction.
Carcinogenicity – Category 2	H351	Suspected of causing cancer.
Specific Target Organ Toxicity - Single Exposure - Category 3	Н335-Н336	May cause respiratory irritation. May cause drowsiness or dizziness.

- · Label elements
- · GHS label elements

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

· Hazard pictograms









GHS02

GHS05

GHS07

GHS08

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· Signal word Danger

Hazard-determining components of labeling:

Tetrabutylammonium Dihydrogen Trifluoride

Methacrylated phosphoric acid ester

· Hazard statements

Flammable liquid and vapour.

Harmful if swallowed.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

Suspected of causing cancer.

May cause respiratory irritation. May cause drowsiness or dizziness.

· Precautionary statements

Obtain special instructions before use.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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

Use explosion-proof [electrical/ventilating/lighting] equipment.

Do not breathe dust/fume/gas/mist/vapours/spray.

Ground and bond container and receiving equipment.

Use non-sparking tools.

Take actions to prevent static discharges.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Contaminated work clothing should not be allowed out of the workplace.

Do not handle until all safety precautions have been read and understood.

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

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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.

Specific treatment (see on this label).

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

Wash contaminated clothing before reuse.

IF exposed or concerned: Get medical advice/attention.

If skin irritation or rash occurs: Get medical advice/attention.

In case of fire: Use for extinction: CO2, powder or water spray.

Take off contaminated clothing and wash it before reuse.

Store locked up.

Store in a well-ventilated place. Keep container tightly closed.

Store in a well-ventilated place. Keep cool.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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



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· HMIS-ratings (scale 0 - 4)



3 Composition/Information on ingredients

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

· Dangerous components:		
CAS: 78-92-2	butanol	20-<25% w/w
CAS: 99337-56-1	Tetrabutylammonium Dihydrogen Trifluoride	≤10% w/w
CAS: 85590-00-7	Methacrylated phosphoric acid ester	3-5% w/w
CAS: 16068-37-4	Bis(triethoxysilyl)ethane	≤1% w/w

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 rinse with water.
- · 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.

Seek immediate medical advice.

- 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:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · 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
 - 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).

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Use neutralizing 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 protection against explosions and fires:

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: 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.
- · 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:

CAS: 78-92-2 butanol

EL Long-term value: 100 ppm EV Short-term value: 150 ppm Long-term value: 100 ppm

- · 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 and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing.

Avoid contact with the eyes and skin.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

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· Protection of hands:



Protective gloves

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

· Material of gloves

Fluorocarbon rubber (Viton)

Butyl rubber, BR

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:	Liquid
Color:	Green
· Odor:	Characteristic
Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	34 °C
· Flammability (solid, gaseous):	Not applicable.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Explosion limits:	
Lower:	1.7 Vol %
Upper:	9.8 Vol %
· Vapor pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.

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· Solubility in / Miscibility with

Water: Fully miscible.

· 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:
- on the skin: Strong caustic effect on skin and mucous membranes.
- · on the eye: Strong caustic effect.
- · Sensitization: Sensitization possible through skin contact.
- $\cdot Additional\ toxicological\ information:$

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

- · Carcinogenic categories
- · 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:
- · 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

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

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· 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. Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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

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•	UN-Number
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· IMDG, IATA

· DOT, TDG, IMDG, IATA

UN2924

· UN proper shipping name

· DOT

Flammable liquids, corrosive, n.o.s. (Butanols, Tetrabutylammonium Dihydrogen Trifluoride)

· ADR/RID/ADN

2924 Flammable liquids, corrosive, n.o.s. (Butanols,

Tetrabutylammonium Dihydrogen Trifluoride)

FLAMMABLE LIQUID, CORROSIVE, N.O.S. (BUTANOLS,

Tetrabutylammonium Dihydrogen Trifluoride)

- · Transport hazard class(es)
- $\cdot DOT$





· Class 3 Flammable liquids

• **Label** 3, 8

· TDG (Transport dangerous goods):





· Class 3 (FC) Flammable liquids

• *Label* 3+8

 \cdot IMDG





· Class 3 Flammable liquids

• *Label* 3/8

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\cdot IATA





· Class	3 Flammable liquids
·Label	3 (8)
Packing group	Ш
· DOT, TDG, IMDG, IATA	III
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids
Danger code (Kemler):	38
EMS Number:	F-E,S-C
· Transport in bulk according to Annex II	of
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	
· ADR/RID/ADN	
· Excepted quantities (EQ)	Code: E1
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
· IMDG	

15 Regulatory information

· Limited quantities (LQ)

· Excepted quantities (EQ)

· UN "Model Regulation":

Safety, health and environmental regulations/legislation specific for the substance or mixture

5L

Code: E1

Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml

UN2924, Flammable liquids, corrosive, n.o.s. (Butanols, Tetrabutylammonium Dihydrogen Trifluoride), 3 (8), III

- ·Sara
- · Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

CAS: 78-92-2 butanol

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

· GHS label elements

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

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· Hazard pictograms









· Signal word Danger

· Hazard-determining components of labeling:

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· Hazard statements

Flammable liquid and vapour.

Harmful if swallowed.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

Suspected of causing cancer.

May cause respiratory irritation. May cause drowsiness or dizziness.

Precautionary statements

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Do not breathe dust/fume/gas/mist/vapours/spray.

Ground and bond container and receiving equipment.

Use non-sparking tools.

Take actions to prevent static discharges.

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Specific treatment (see on this label).

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

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IF exposed or concerned: Get medical advice/attention.

If skin irritation or rash occurs: Get medical advice/attention.

In case of fire: Use for extinction: CO2, powder or water spray.

Take off contaminated clothing and wash it before reuse.

Store locked up.

Store in a well-ventilated place. Keep container tightly closed.

Store in a well-ventilated place. Keep cool.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· 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.

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· 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 09/22/2016 / 2
- · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.