

Printing date 09/21/2016 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.

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 SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) identification

· Classification of the substance or mixture

Flam. Liq. 3 H226 Flammable liquid and vapor.

Acute Tox. 4 H302 Harmful if swallowed.

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

Eye Dam. 1 H318 Causes serious eye damage.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335-H336 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

S02 GHS05

05 GHSC

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

Tetrabutylammonium Dihydrogen Trifluoride Methacrylated phosphoric acid ester

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butanol

· Hazard statements

Flammable liquid and vapor.

Harmful if swallowed.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

May cause respiratory irritation. May cause drowsiness or dizziness.

· 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.

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

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



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Health = 3

Fire = 3

Reactivity = 0
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· HMIS-ratings (scale 0 - 4)



- · 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:			
CAS: 78-92-2	butanol	20-<25%	
CAS: 99337-56-1	Tetrabutylammonium Dihydrogen Trifluoride	≤10%	
CAS: 85590-00-7	Methacrylated phosphoric acid ester	2.5-<10%	
CAS: 16068-37-4	Bis(triethoxysilyl)ethane	1-<2.5%	

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.

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· 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 Fire-fighting 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).

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.

HS

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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

PEL Long-term value: 450 mg/m³, 150 ppm
REL Short-term value: 455 mg/m³, 150 ppm
Long-term value: 305 mg/m³, 100 ppm
TLV Long-term value: 300 mg/m³, 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.

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

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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 (93 °F)
Flammability (solid, gaseous):	Not applicable.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product is not explosive. However, formation of explosive air/vapo 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.
Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient (n-octanol/wa	ter): 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.

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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
- · 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.

- · 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. 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.

· UN-Number · DOT, ADR,RID,ADN, 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)
IMDG, IATA	FLAMMABLE LIQUID, CORROSIVE, N.O.S. (BUTANOLS,
,	Tetrabutylammonium Dihydrogen Trifluoride)

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(Contd. of page 6) · Transport hazard class(es) $\cdot DOT$ · Class 3 Flammable liquids ·Label 3, 8 · ADR/RID/ADN 3 (FC) Flammable liquids · Class \cdot Label 3+8 · IMDG · Class 3 Flammable liquids ·Label 3/8 \cdot IATA · Class 3 Flammable liquids ·Label 3 (8) · Packing group · DOT, ADR, RID, ADN, IMDG, IATA III· Environmental hazards: · Marine pollutant: No · Special precautions for user Warning: Flammable liquids · Danger code (Kemler): · 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 Code: E1 · Excepted quantities (EQ) Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml · IMDG · 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
· UN ''Model Regulation'':	UN2924, Flammable liquids, corrosive, n.o.s. (Butanols, Tetrabutylammonium Dihydrogen Trifluoride), 3 (8), III

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):

CAS: 78-92-2 butanol

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · 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







GHS02

GHS05

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

Tetrabutylammonium Dihydrogen Trifluoride Methacrylated phosphoric acid ester butanol

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· Hazard statements

Flammable liquid and vapor.

Harmful if swallowed.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

May cause respiratory irritation. May cause drowsiness or dizziness.

· 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.

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

· 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 09/21/2016 / 2

· 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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

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

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

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* * Data compared to the previous version altered.