

Printing date 18.10.2019 Version number 4 Revision: 18.10.2019

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- · Trade name: Monobond Etch & Prime
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Ceramic primer
- 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

Flam. Liq. 3 H226 Flammable liquid and vapour.

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 labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms







GHS02

GHS05

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

tetrabutylammonium dihydrogen trifluoride

Bis(triethoxysilyl)ethane

methacrylated phosphoric acid ester

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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.

May cause respiratory irritation. May cause drowsiness or dizziness.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Do not breathe dusts or mists.

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

Immediately call a POISON CENTER/doctor.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

Store locked up.

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

- · 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: 78-92-2	butanol	10-25%
	Flam. Liq. 3, H226; Eye Irrit. 2, H319; STOT SE 3, H335-H336	
CAS: 99337-56-1	tetrabutylammonium dihydrogen trifluoride Acute Tox. 3, H301; Acute Tox. 3, H311; Skin Corr. 1C, H314; Eye Dam. 1, H318; Acute Tox. 4, H332	2.5-10%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	2.5-10%
CAS: 16068-37-4	Bis(triethoxysilyl)ethane Acute Tox. 3, H301	<2.5%

[·] 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:

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.

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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:

CO2, 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.
- · Additional information See Section 14 for Hazchem Code.

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 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:

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 container tightly sealed.
- · Specific end use(s) No further relevant information available.

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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: 78-92-2 butanol

NES Long-term value: 303 mg/m³, 100 ppm WES Long-term value: 303 mg/m³, 100 ppm

- · 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.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing

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 (EN 374)

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

· Material of gloves

Fluorocarbon rubber (Viton)

Butyl rubber, BR

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 (EN 166)

9 Physical and Chemical Properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Liquid
Colour: Green
Odour: Characteristic
Odour threshold: Not determined.

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pH-value:	Not determined.
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range.	: Undetermined.
Flash point:	34 °C
Flammability (solid, gas):	Not applicable.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation of explosive air/
	vapour mixtures are possible.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
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
- · Skin corrosion/irritation Caustic effect on skin and mucous membranes.
- · Serious eye damage/irritation Strong irritant with the danger of severe eye injury.
- · Respiratory or skin sensitisation Sensitisation 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.

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.
- · 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.

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

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

141	ranspor	tinj	tormat	tion

· UN-Number · ADG, IMDG, IATA	UN2924
· UN proper shipping name · ADG	2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (BUTANOLS, tetrabutylammonium dihydrogen
· IMDG, IATA	trifluoride) FLAMMABLE LIQUID, CORROSIVE, N.O.S. (BUTANOLS, tetrabutylammonium dihydrogen

trifluoride)

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





Class 3 (FC) Flammable liquids.

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Label	3+8
IMDG	
Class Label	3 Flammable liquids. 3/8
IATA	
Class	3 Flammable liquids.
Label	3 (8)
Packing group	
ADG, IMDG, IATA	III
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	38 •3W
Hazchem or Emergency Action Code: EMS Number:	•5 W F-E,S-C
Stowage Category	A
Stowage Code	SW2 Clear of living quarters.
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 (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	D/E
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'':	UN 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.
	(BUTANOLS, TETRABUTYLAMMONIUM
	DIHYDROGEN TRIFLUORIDE), 3 (8), III

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15 Regulatory information

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

· Australian Inventory of Chemical Substances	
CAS: 78-92-2	butanol
CAS: 16068-37-4	Bis(triethoxysilyl)ethane

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· GHS label elements

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

Hazard pictograms







GHS07

GHS02

02 GHS05

· Signal word Danger

· Hazard-determining components of labelling:

tetrabutylammonium dihydrogen trifluoride

Bis(triethoxysilyl)ethane

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.

May cause respiratory irritation. May cause drowsiness or dizziness.

Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Do not breathe dusts or mists.

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

Immediately call a POISON CENTER/doctor.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

Store locked up.

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

· Directive 2012/18/EU

- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category P5c FLAMMABLE LIQUIDS
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 5000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50000 t
- · 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.

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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

H226 Flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids - Category 3

Acute Tox. 3: Acute toxicity - Category 3

Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1C: Skin corrosion/irritation – Category 1C

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

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