

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

Revision: 29.05.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: Monobond Etch & Prime**
- **1.2 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
- **1.3 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
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
- Flam. Liq. 3 H226 Flammable liquid and vapour.
- Acute Tox. 4 H332 Harmful if inhaled.
- Skin Corr. 1C H314 Causes severe skin burns and eye damage.
- Eye Dam. 1 H318 Causes serious eye damage.
- STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.

- **Hazard pictograms**



GHS02 GHS05 GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**
tetrabutylammonium dihydrogen trifluoride
butanol
- **Hazard statements**
H226 Flammable liquid and vapour.
H332 Harmful if inhaled.
H314 Causes severe skin burns and eye damage.
H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

Revision: 29.05.2024

Trade name: Monobond Etch & Prime

(Contd. of page 1)

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P403+P235 Store in a well-ventilated place. Keep cool.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 78-92-2 EINECS: 201-158-5 Reg.nr.: 01-2119475146-36-XXXX	butanol Eye Irrit. 2, H319; STOT SE 3, H335-H336	20-25%
CAS: 99337-56-1	tetrabutylammonium dihydrogen trifluoride Skin Corr. 1C, H314; Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332	5-10%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<10%
CAS: 16068-37-4 EINECS: 240-212-2	Bis(triethoxysilyl)ethane Acute Tox. 3, H301; Acute Tox. 4, H312; Eye Irrit. 2, H319	<2.5%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 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.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 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

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

Revision: 29.05.2024

Trade name: **Monobond Etch & Prime**

(Contd. of page 2)

- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 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 section 13.
Ensure adequate ventilation.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 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.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

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

CAS: 78-92-2 butanol

WEL	Short-term value: 462 mg/m ³ , 150 ppm
	Long-term value: 308 mg/m ³ , 100 ppm

- **Regulatory information** WEL: EH40/2020
- **Additional information:** The lists valid during the making were used as basis.

· 8.2 Exposure controls

- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

Revision: 29.05.2024

Trade name: Monobond Etch & Prime

(Contd. of page 3)

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.

· **Hand protection**



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/face protection**



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· Colour:	Green
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	34 °C
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

Revision: 29.05.2024

Trade name: **Monobond Etch & Prime**

(Contd. of page 4)

· Vapour density	<i>Not determined.</i>
· 9.2 Other information	
· Appearance:	
· Form:	<i>Liquid</i>
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	<i>Product is not selfigniting.</i>
· Explosive properties:	<i>Product is not explosive. However, formation of explosive air/vapour mixtures are possible.</i>
· Change in condition	
· Evaporation rate	<i>Not determined.</i>
· Information with regard to physical hazard classes	
· Explosives	<i>Void</i>
· Flammable gases	<i>Void</i>
· Aerosols	<i>Void</i>
· Oxidising gases	<i>Void</i>
· Gases under pressure	<i>Void</i>
· Flammable liquids	<i>Flammable liquid and vapour.</i>
· Flammable solids	<i>Void</i>
· Self-reactive substances and mixtures	<i>Void</i>
· Pyrophoric liquids	<i>Void</i>
· Pyrophoric solids	<i>Void</i>
· Self-heating substances and mixtures	<i>Void</i>
· Substances and mixtures, which emit flammable gases in contact with water	<i>Void</i>
· Oxidising liquids	<i>Void</i>
· Oxidising solids	<i>Void</i>
· Organic peroxides	<i>Void</i>
· Corrosive to metals	<i>Void</i>
· Desensitised explosives	<i>Void</i>

SECTION 10: Stability and reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability** *Stable under normal handling and storage conditions.*
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **10.3 Possibility of hazardous reactions** *No dangerous reactions known.*
- **10.4 Conditions to avoid** *No further relevant information available.*
- **10.5 Incompatible materials:** *No further relevant information available.*
- **10.6 Hazardous decomposition products:** *None under normal conditions of storage and use.*

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity**
Harmful if inhaled.
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation** *Based on available data, the classification criteria are not met.*
- **Germ cell mutagenicity** *Based on available data, the classification criteria are not met.*

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

Revision: 29.05.2024

Trade name: Monobond Etch & Prime

(Contd. of page 5)

- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**
May cause respiratory irritation. May cause drowsiness or dizziness.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **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.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
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.

SECTION 14: Transport information

- | | |
|--|---|
| <ul style="list-style-type: none"> · 14.1 UN number or ID number · ADR/RID/ADN, IMDG, IATA | UN2924 |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR/RID/ADN | 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S.
(BUTANOLS, tetrabutylammonium dihydrogen trifluoride) |
| <ul style="list-style-type: none"> · IMDG, IATA | FLAMMABLE LIQUID, CORROSIVE, N.O.S.
(BUTANOLS, tetrabutylammonium dihydrogen trifluoride) |

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

Revision: 29.05.2024

Trade name: **Monobond Etch & Prime**

(Contd. of page 6)

· 14.3 Transport hazard class(es)

· ADR/RID/ADN



· Class 3 (FC) Flammable liquids.
 · Label 3+8

· IMDG



· Class 3 Flammable liquids.
 · Label 3/8

· IATA



· Class 3 Flammable liquids.
 · Label 3 (8)

· 14.4 Packing group

· ADR/RID/ADN, IMDG, IATA III

· 14.5 Environmental hazards: Not applicable.

· 14.6 Special precautions for user Warning: Flammable liquids.

· Hazard identification number (Kemler code): 38

· EMS Number: F-E,S-C

· Stowage Category A

· Stowage Code SW2 Clear of living quarters.

· 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

· Transport/Additional information:

· ADR/RID/ADN

· 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

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

Revision: 29.05.2024

Trade name: **Monobond Etch & Prime**

(Contd. of page 7)

· UN "Model Regulation":	UN 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (BUTANOLS, TETRABUTYLAMMONIUM DIHYDROGEN TRIFLUORIDE), 3 (8), III
--------------------------	---

SECTION 15: Regulatory information

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

· Poisons Act

· Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

· 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 Regulation 2017/745 on Medical Devices (MDR).

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

· Classification according to Regulation (EC) No 1272/2008

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· Abbreviations and acronyms:

IMO: International Maritime Organization

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

(Contd. on page 9)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.05.2024

Version number 4 (replaces version 3)

Revision: 29.05.2024

Trade name: Monobond Etch & Prime

(Contd. of page 8)

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

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

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

-GB-