

Safety Data Sheet according to WHS Regulations

Printing date 29.08.2024

Version number 9

Revision: 05.02.2024

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name:** **Monobond Plus**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Universal 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@ivoclar.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Flammable liquids – Category 2 H225 Highly flammable liquid and vapour.
Eye damage/irritation – Category 2A H319 Causes serious eye irritation.
Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.
- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**
 
GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
sulphide methacrylate (<2.5 %)
methacrylated phosphoric acid ester (1 %)
- **Hazard statements**
Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause an allergic skin reaction.

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- **Precautionary statements**

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

Keep container tightly closed.

Avoid breathing dust/fume/gas/mist/vapours/spray.

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

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

Store in a well-ventilated place. Keep cool.

- **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: 64-17-5	ethanol Flammable liquids – Category 2, H225; Eye damage/irritation – Category 2A, H319	50-100%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	<2.5%
CAS: 1096164-11-2	sulphide methacrylate Acute toxicity - oral – Category 4, H302; Acute toxicity - dermal – Category 4, H312; Acute toxicity - inhalation – Category 4, H332; Skin corrosion/irritation – Category 2, H315; Skin sensitisation – Category 1, H317; Specific target organ toxicity (single exposure) – Category 3, H335	<2.5%

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

4 First Aid Measures

- **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.

- **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.

If symptoms persist consult doctor.

- **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

- **Suitable extinguishing agents:**

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

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

- **Protective equipment:** No special measures required.

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- **Additional information**
Cool endangered receptacles with water spray.
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).
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.
- **Information about fire - and explosion protection:** No special measures required.
- **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:**
Protect from heat and direct sunlight.
Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.

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

CAS: 64-17-5 ethanol

WES Long-term value: 1880 mg/m³, 1000 ppm

- **Additional information:** The lists valid during the making were used as basis.
- **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.
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.

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· **Protection of hands:**



Protective gloves (EN 374)

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

· **Material of gloves**

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.

· **Not suitable are gloves made of the following materials:**

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

· **Eye protection:**



Tightly sealed goggles (EN 166)

9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· Form:	Fluid
· Colour:	Colourless
· Odour:	Alcohol-like
· Odour threshold:	Not determined.
· pH-value:	Not determined.

· **Change in condition**

· Melting point/freezing point:	-114.5 °C
· Initial boiling point and boiling range:	78 °C
· Flash point:	13 °C
· Auto-ignition temperature:	425 °C
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· **Explosion limits:**

· Lower:	3.5 Vol %
· Upper:	15 Vol %
· Vapour pressure at 20 °C:	59 hPa
· Vapour pressure at 50 °C:	280 hPa
· Density at 20 °C:	0.794 g/cm ³
· 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.

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· Solvent content:	
· Organic solvents:	96.0 %
· Solids content:	0.0 %
· 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** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

Oral	LD50	>5000 mg/kg (rat)
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CAS: 64-17-5 ethanol

Oral	LD50	7060 mg/kg (rat)
Inhalative	LC50/4 h	20000 mg/l (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.
- **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.

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.

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- **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.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|--|--|
| <ul style="list-style-type: none"> · UN-Number · ADG, IMDG, IATA | <p>UN1170</p> |
| <ul style="list-style-type: none"> · UN proper shipping name · ADG · IMDG · IATA | <p>1170 ETHANOL (ETHYL ALCOHOL) solution
ETHANOL (ETHYL ALCOHOL) solution
ETHANOL solution</p> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADG | <p>3 (F1) Flammable liquids.</p> |
| <div style="text-align: center;">  </div> <ul style="list-style-type: none"> · Class · Label | <p>3</p> |
| <div style="text-align: center;">  </div> <ul style="list-style-type: none"> · Class · Label | <p>3 Flammable liquids.</p> |
| <ul style="list-style-type: none"> · IMDG, IATA | <p>3</p> |
| <ul style="list-style-type: none"> · Packing group · ADG, IMDG, IATA | <p>II</p> |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | <p>No</p> |
| <ul style="list-style-type: none"> · Special precautions for user · Hazard identification number (Kemler code): · Hazchem or Emergency Action Code: · EMS Number: · Stowage Category | <p>Warning: Flammable liquids.
33
•2YE
F-E,S-D
A</p> |

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· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADG	1L
· Limited quantities (LQ)	Code: E2
· Excepted quantities (EQ)	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1170 ETHANOL (ETHYL ALCOHOL) SOLUTION, 3, II

15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

CAS: 64-17-5 ethanol

· **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**



GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**

sulphide methacrylate (<2.5 %)

methacrylated phosphoric acid ester (1 %)

· **Hazard statements**

Highly flammable liquid and vapour.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

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

Keep container tightly closed.

Avoid breathing dust/fume/gas/mist/vapours/spray.

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

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

Store in a well-ventilated place. Keep cool.

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- **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).
- **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.

- **Relevant phrases**
H225 Highly flammable liquid and vapour.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
- **Contact:**
- **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
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flammable liquids – Category 2: Flammable liquids – Category 2
Acute toxicity - oral – Category 4: Acute toxicity – Category 4
Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2
Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
Skin sensitisation – Category 1: Skin sensitisation – Category 1
Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3
- *** Data compared to the previous version altered.**

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