

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

Printing date 09.01.2014

Version number 10

Revision: 17.12.2013

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

- **1.1 Product identifier**
- **Trade name: Monobond-S**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** Bonding agent
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
-
- **Tel:** +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
msds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

* **SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
.....
R10: Flammable.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **2.2 Label elements**
- **Labelling according to EU guidelines:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Risk phrases:**
10 Flammable.
- **Safety phrases:**
7 Keep container tightly closed.
16 Keep away from sources of ignition - No smoking.
60 This material and its container must be disposed of as hazardous waste.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

* **SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

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· Dangerous components:

CAS: 64-17-5	ethanol	F R11	50-100%
EINECS: 200-578-6			

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Rinse with water.
Generally the product does not irritate the skin.
- **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.
- **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.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** Cool endangered receptacles with water spray.

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:**
Dilute with plenty of water.
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).
- **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** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.

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Protect against electrostatic charges.

- **7.2 Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** No special requirements.

- **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

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

- **8.1 Control parameters**

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

64-17-5 ethanol

WEL Long-term value: 1920 mg/m ³ , 1000 ppm
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- **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Usual hygienic measures for dental practice.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

- **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:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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

- **Material of gloves**

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:** Safety glasses

SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Fluid
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Colour:	Colourless
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- **Odour:** Alcohol-like

- **Odour threshold:** Not determined.

- **pH-value at 20 °C:** 4

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· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	25 °C
· Ignition temperature:	425 °C
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits:	
Lower:	3.5 Vol %
Upper:	15.0 Vol %
· Vapour pressure at 20 °C:	59 hPa
· Density at 20 °C:	0.913 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.
· 9.2 Other information	No further relevant information available.

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 toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

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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.
- **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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
 - **European waste catalogue**
- | | |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing dangerous substances |
|-----------|--|
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- | | |
|---|--|
| · 14.1 UN-Number | |
| · ADR, IMDG, IATA | 1170 |
| · 14.2 UN proper shipping name | |
| · ADR | 1170 ETHANOL (ETHYL ALCOHOL), solution |
| · IMDG | ETHANOL (ETHYL ALCOHOL), solution |
| · IATA | ETHANOL, solution |
| · 14.3 Transport hazard class(es) | |
| · ADR | |
|  | |
| · Class | 3 (F1) Flammable liquids. |
| · Label | 3 |

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· **IMDG, IATA**

- **Class** 3 Flammable liquids.
- **Label** 3

- **14.4 Packing group**
- **ADR, IMDG, IATA** III

- **14.5 Environmental hazards:**
- **Marine pollutant:** No

- **14.6 Special precautions for user** Warning: Flammable liquids.
- **Danger code (Kemler):** 30
- **EMS Number:** F-E,S-D

- **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **Transport/Additional information:**

- **ADR**
- **Limited quantities (LQ)** LQ7
- **Transport category** 3
- **Tunnel restriction code** D/E

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
- **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**
R11 Highly flammable.
- *** Data compared to the previous version altered.**