

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.01.2011





Version number 5

Revision: 24.01.2011

## 1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** **Monobond Plus**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation**  
Universal primer mediating a bond between metal, glass/oxid ceramics and resin
- **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
- **Emergency telephone number:** +423 / 235 33 13

## 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
 Xi; Sensitising  
R43: May cause sensitisation by skin contact.
-  F; Highly flammable  
R11: Highly flammable.
- **Information concerning particular hazards for human and environment:**  
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **Label elements**
- **Labelling according to EU guidelines:**  
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
- **Code letter and hazard designation of product:**  
  Xi Irritant  
F Highly flammable
- **Hazard-determining components of labelling:**  
Methacrylated phosphoric acid ester
- **Risk phrases:**  
11 Highly flammable.  
43 May cause sensitisation by skin contact.
- **Safety phrases:**  
7/9 Keep container tightly closed and in a well-ventilated place.  
16 Keep away from sources of ignition - No smoking.

(Contd. on page 2)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 24.01.2011

Version number 5

Revision: 24.01.2011

Trade name: **Monobond Plus**

(Contd. of page 1)





- 23 Do not breathe fumes/aerosol.
- 24 Avoid contact with skin.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.

- **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 substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6	ethanol	 F R11	50-100%
CAS: 2530-85-0 EINECS: 219-785-8	3-trimethoxysilylpropyl methacrylate	 Xi R36/37/38	≤ 2.5%
CAS: 85590-00-7	Methacrylated phosphoric acid ester	 Xi R36/38;  Xi R43	≤ 2.5%

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

### 4 First aid measures

- **Description of 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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** Cool endangered receptacles with water spray.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**  
Dilute with plenty of water.

(Contd. on page 3)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 24.01.2011

Version number 5

Revision: 24.01.2011

Trade name: **Monobond Plus**

(Contd. of page 2)

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** Ensure good ventilation/exhaustion at the workplace.

· **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 in a cool location.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:**

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

· **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/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:**

**64-17-5 ethanol**

WEL () Long-term value: 1920 mg/m<sup>3</sup>, 1000 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.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· **Respiratory protection:** Not necessary if room is well-ventilated.

· **Protection of hands:**



Protective gloves

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **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

(Contd. on page 4)

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

Printing date 24.01.2011

Version number 5

Revision: 24.01.2011

Trade name: **Monobond Plus**

(Contd. of page 3)

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.

- **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

## 9 Physical and chemical properties

- **Information on basic 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/Melting range:	-114.5°C
Boiling point/Boiling range:	78°C

Flash point:	13°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 Vol %

Vapour pressure at 20°C:	59 hPa
--------------------------	--------

Density at 20°C:	0.794 g/cm <sup>3</sup>
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

Solubility in / Miscibility with water:	Soluble.
---	----------

Segregation 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.

(Contd. on page 5)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 24.01.2011

Version number 5

Revision: 24.01.2011

Trade name: **Monobond Plus**

(Contd. of page 4)

- **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:**

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

Oral	LD50	>6000 mg/kg (rat)
------	------	-------------------

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Irritant
- **Sensitisation** May cause sensitisation by skin contact.

### 12 Ecological information

- **Toxicity**
- **Acquatic 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.

- **European waste catalogue**

18 01 06*	chemicals consisting of or containing dangerous substances
-----------	--

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

(Contd. on page 6)

GB

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

Printing date 24.01.2011

Version number 5

Revision: 24.01.2011

Trade name: **Monobond Plus**

(Contd. of page 5)

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### 14 Transport information

· **Land transport ADR/RID (cross-border)**



- **ADR/RID class:** 3 (F1) Flammable liquids.
- **Danger code (Kemler):** 33
- **UN-Number:** 1170
- **Packaging group:** II
- **Hazard label:** 3
- **UN proper shipping name:** 1170 ETHANOL (ETHYL ALCOHOL), solution
- **Tunnel restriction code** D/E

· **Maritime transport IMDG:**



- **IMDG Class:** 3
- **UN Number:** 1170
- **Label** 3
- **Packaging group:** II
- **EMS Number:** F-E,S-D
- **Marine pollutant:** No
- **Proper shipping name:** ETHANOL (ETHYL ALCOHOL), solution

· **Air transport ICAO-TI and IATA-DGR:**



- **ICAO/IATA Class:** 3
- **UN/ID Number:** 1170
- **Label** 3
- **Packaging group:** II
- **Proper shipping name:** ETHANOL, solution

- **Special precautions for user** Warning: Flammable liquids.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

### 15 Regulatory information

- **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 EC-directive 93/42/EEC.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

GB

(Contd. on page 7)

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

Printing date 24.01.2011

Version number 5

Revision: 24.01.2011

**Trade name: Monobond Plus**

(Contd. of page 6)

**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.*
- R36/37/38 *Irritating to eyes, respiratory system and skin.*
- R36/38   *Irritating to eyes and skin.*
- R43      *May cause sensitisation by skin contact.*

GB