

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

Printing date 06.02.2014

Version number 1

Revision: 04.02.2014

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

- **1.1 Product identifier**
- **Trade name:** **Adhese Universal**
- **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** Light-curing, single-component dental adhesive
- **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**
Xi; Irritant
R36/38: Irritating to eyes and skin.
.....
Xi; Sensitising
R43: May cause sensitisation by skin contact.
.....
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.
- **Code letter and hazard designation of product:**



Xi Irritant

- **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
Bis-GMA
decamethylene dimethacrylate
Methacrylated phosphoric acid ester
2-dimethylaminoethyl methacrylate

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· **Risk phrases:**

- 10 Flammable.
- 36/38 Irritating to eyes and skin.
- 43 May cause sensitisation by skin contact.

· **Safety phrases:**

- 7 Keep container tightly closed.
- 16 Keep away from sources of ignition - No smoking.
- 24 Avoid contact with skin.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 37 Wear suitable gloves.
- 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.

· **Dangerous components:**

CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate	Xi R36/38; Xi R43	20-25%
CAS: 1565-94-2	Bis-GMA	Xi R36/38; Xi R43	20-25%
CAS: 64-17-5 EINECS: 200-578-6	ethanol	F R11	10-25%
CAS: 6701-13-9 EINECS: 229-745-1	decamethylene dimethacrylate	Xi R36; Xi R43	2.5-10%
CAS: 85590-00-7	Methacrylated phosphoric acid ester	Xi R36/38; Xi R43	2.5-10%
CAS: 10373-78-1	campherquinone	Xi R36/37/38	< 2.5%
CAS: 2867-47-2 EINECS: 220-688-8	2-dimethylaminoethyl methacrylate	Xn R21/22; Xi R36/38; Xi R43	1-<2.5%
CAS: 128-37-0 EINECS: 204-881-4	2,6-di-tert-butyl-p-cresol	Xn R22; Xi R36/38; N R51/53	<2.5%

- **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 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.
- If skin irritation continues, consult a doctor.

· **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.

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- **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.

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).
- **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.
- **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:**
Protect from exposure to the light.
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.

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· 8.1 Control parameters

· **Ingredients with limit values that require monitoring at the workplace:****64-17-5 ethanol**WEL Long-term value: 1920 mg/m³, 1000 ppm· **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.

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

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:** Safety glasses**SECTION 9: Physical and chemical properties**

· 9.1 Information on basic physical and chemical properties

· **General Information**· **Appearance:****Form:** Liquid**Colour:** Yellow· **Odour:** Characteristic· **Odour threshold:** Not determined.· **pH-value:** Not applicable.· **Change in condition****Melting point/Melting range:** Undetermined.**Boiling point/Boiling range:** Undetermined.· **Flash point:** 36 °C· **Self-igniting:** Product is not selfigniting.· **Danger of explosion:** Product does not present an explosion hazard.

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· 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.
· 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**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **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:** Irritant to skin and mucous membranes.
- **on the eye:** 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

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.

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- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product 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**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- **European waste catalogue**

18 01 06*	chemicals consisting of or containing dangerous substances
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|---|
| · 14.1 UN-Number
· ADR, IMDG, IATA | UN1993 |
| · 14.2 UN proper shipping name
· ADR
· IMDG
· IATA | 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL))
FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL))
FLAMMABLE LIQUID, N.O.S. (ETHANOL) |
| · 14.3 Transport hazard class(es)
· ADR | |
|  | |
| · Class
· Label | 3 (F1) Flammable liquids.
3 |
| · IMDG, IATA | |
|  | |
| · Class
· Label | 3 Flammable liquids.
3 |
| · 14.4 Packing group
· ADR, IMDG, IATA | III |

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· 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-E
· 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)	5L
· 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.
- R21/22 Harmful in contact with skin and if swallowed.
- R22 Harmful if swallowed.
- R36 Irritating to eyes.
- R36/37/38 Irritating to eyes, respiratory system and skin.
- R36/38 Irritating to eyes and skin.
- R43 May cause sensitisation by skin contact.
- R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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