

**Safety data sheet**  
**according to Regulation (EC) No 1907/2006, Article 31**

Printing date 24.09.2024




Version number 7 (replaces version 6)

Revision: 03.09.2024

**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  
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.  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2 H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
Repr. 1B H360 May damage fertility or the unborn child.
  - **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

GHS07

GHS08
- **Signal word** *Danger*
  - **Hazard-determining components of labelling:**  
2-hydroxyethyl methacrylate  
ethyl p-dimethylaminobenzoate  
1,10-decandiol dimethacrylate  
methacrylated phosphoric acid ester  
2-dimethylaminoethyl methacrylate
  - **Hazard statements**  
H226 Flammable liquid and vapour.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.  
H360 May damage fertility or the unborn child.

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· **Precautionary statements**

- P201 Obtain special instructions before use.
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- 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.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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: 868-77-9 EINECS: 212-782-2 Reg.nr.: 01-2119490169-29-xxxx	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
CAS: 64-17-5 EINECS: 200-578-6 Reg.nr.: 01-2119457610-43-xxxx	ethanol Flam. Liq. 2, H225; Eye Irrit. 2, H319	10-25%
CAS: 6701-13-9 EINECS: 229-745-1 Reg.nr.: 01-2120735533-57-0000	1,10-decandiol dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-<10%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-<10%
CAS: 10373-78-1	camphorquinone Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	<2.5%
CAS: 2867-47-2 EINECS: 220-688-8	2-dimethylaminoethyl methacrylate Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	1-<2.5%
CAS: 10287-53-3 EINECS: 233-634-3 Reg.nr.: 01-2120766020-67-XXXX	ethyl p-dimethylaminobenzoate Repr. 1B, H360; Aquatic Chronic 2, H411	0.3-<2.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Chronic 1, H410	0.025-<0.25%

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

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#### 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.
- **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:**  
CO<sub>2</sub>, 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.

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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: 64-17-5 ethanol**WEL Long-term value: 1920 mg/m<sup>3</sup>, 1000 ppm**CAS: 128-37-0 Butylated hydroxytoluene**WEL Long-term value: 10 mg/m<sup>3</sup>· **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.

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**

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/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:** Yellow· **Odour:** Characteristic

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· <b>Odour threshold:</b>	Not determined.
· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Boiling point or initial boiling point and boiling range</b>	Undetermined.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Flash point:</b>	36 °C (ASTM D7094)
· <b>pH</b>	Not applicable.
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>Dynamic:</b>	Not determined.
· <b>Solubility</b>	
· <b>water:</b>	Fully miscible.
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density and/or relative density</b>	
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· <b>Form:</b>	Liquid
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Flammable liquid and vapour.
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.

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- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
  - **Acute toxicity** Based on available data, the classification criteria are not met.
  - **LD/LC50 values relevant for classification:**
- |   |          |                  |
|---|----------|------------------|
| <b>CAS: 2867-47-2 2-dimethylaminoethyl methacrylate</b> |          |                  |
| Oral  | LD50     | 1751 mg/kg (rat) |
| Inhalative  | LC50/4 h | 0.62 mg/l (rat)  |
- **Skin corrosion/irritation**  
Causes skin irritation.
  - **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**  
May damage fertility or the unborn child.
  - **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.
  - **11.2 Information on other hazards**

#### · Endocrine disrupting properties

CAS: 128-37-0 Butylated hydroxytoluene

List II

### 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** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects** No further relevant information available.
- **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.

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### 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

- |   |  |
|---|--|
| · <b>14.1 UN number or ID number</b>  | UN1170   |
| · <b>ADR/RID/ADN, IMDG, IATA</b>  |  |
| · <b>14.2 UN proper shipping name</b>   | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · <b>ADR/RID/ADN</b>  | ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)      |
| · <b>IMDG</b>   | ETHANOL SOLUTION                               |
| · <b>IATA</b>   |  |
| · <b>14.3 Transport hazard class(es)</b>  |  |
| · <b>ADR/RID/ADN</b>  |  |
|  |  |
| · <b>Class</b>  | 3 (F1) Flammable liquids.                      |
| · <b>Label</b>  | 3  |
| · <b>IMDG, IATA</b>   |  |
|  |  |
| · <b>Class</b>  | 3 Flammable liquids.                           |
| · <b>Label</b>  | 3  |
| · <b>14.4 Packing group</b>   | III  |
| · <b>ADR/RID/ADN, IMDG, IATA</b>  |  |
| · <b>14.5 Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>  | No   |
| · <b>14.6 Special precautions for user</b>  | Warning: Flammable liquids.                    |
| · <b>Hazard identification number (Kemler code):</b>                                | 30   |
| · <b>EMS Number:</b>  | F-E,S-D  |
| · <b>Stowage Category</b>   | A  |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b>               | Not applicable.                                |

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#### · 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

##### · UN "Model Regulation":

UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, 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

#### · 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

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.

H335 May cause respiratory irritation.

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*H360 May damage fertility or the unborn child.*

*H410 Very toxic to aquatic life with long lasting effects.*

*H411 Toxic to aquatic life with long lasting effects.*

**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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 1B: Reproductive toxicity – Category 1B

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

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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

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