

Safety Data Sheet in accordance with HSNO

Printing date 12.12.2019



Version number 5

Revision: 12.12.2019

1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** ***Adhese Universal***
- **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*
- **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*
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- **Importer:**
*Ivoclar Vivadent Ltd
12 Omega St, Rosedale, Auckland
New Zealand
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990*
- **Further information obtainable from:**
*Regulatory Affairs
sds@ivoclarvivadent.com*
- **Emergency telephone number:** *0800 764 766 (National Poison Centre - 24 hours / 7 days)*

2 Hazards identification

- **Classification of the substance or mixture**
*Flam. Liq. 3 H226 Flammable liquid and vapour.
Acute Tox. 5 H333 May be harmful if inhaled.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 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** *Warning*
 - **Hazard-determining components of labelling:**
*2-hydroxyethyl methacrylate
2-dimethylaminoethyl methacrylate
Bis-GMA
1,10-decandiol dimethacrylate
methacrylated phosphoric acid ester*
 - **Hazard statements**
*Flammable liquid and vapour.
May be harmful if inhaled.*

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Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

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

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.

If eye irritation persists: Get medical advice/attention.

· **Additional information:**

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 Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/Information on ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
CAS: 36425-15-7 NLP: 500-089-0	Bis-GMA Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	10-25%
CAS: 64-17-5 EINECS: 200-578-6	ethanol Flam. Liq. 2, H225	10-25%
CAS: 6701-13-9 EINECS: 229-745-1	1,10-decandiol dimethacrylate Eye Irrit. 2A, H319; Skin Sens. 1, H317	2.5-10%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	2.5-10%
CAS: 10373-78-1	camphorquinone Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	<2.5%
CAS: 2867-47-2 EINECS: 220-688-8	2-dimethylaminoethyl methacrylate Acute Tox. 2, H330; Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; Flam. Liq. 4, H227	<2.5%

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

4 First aid measures

· **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.

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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

- **Extinguishing media**
- **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.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

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).
- **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:**
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 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.
- **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.

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- **Control parameters**

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

CAS: 64-17-5 ethanol

WES	Long-term value: 1880 mg/m ³ , 1000 ppm
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- **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 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.

- **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:**



Tightly sealed goggles

9 Physical and chemical properties

- **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/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

- **Flash point:** 36 °C (ASTM D7094)

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· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· 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.
· 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**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **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**
- **Skin corrosion/irritation** Irritant to skin and mucous membranes.
- **Serious eye damage/irritation** Irritating effect.
- **Respiratory or skin sensitisation** Sensitisation 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

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.

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- **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 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **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**
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.

14 Transport information

- | | |
|--|---|
| <ul style="list-style-type: none"> · UN-Number · ADR/RID/ADN, IMDG, IATA | UN1170 |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR/RID/ADN · IMDG · IATA | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), ENVIRONMENTALLY HAZARDOUS ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
ETHANOL SOLUTION |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADR/RID/ADN | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class · Label | 3 (F1) Flammable liquids.
3 |
| <ul style="list-style-type: none"> · IMDG, IATA | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class · Label | 3 Flammable liquids.
3 |
| <ul style="list-style-type: none"> · Packing group · ADR/RID/ADN, IMDG, IATA | III |

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· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	30
· EMS Number:	F-E,S-D
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· 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, ENVIRONMENTALLY HAZARDOUS

15 Regulatory information

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

· **New Zealand Inventory of Chemicals**

All ingredients are listed.

· **HSNO Approval numbers**

CAS: 868-77-9	2-hydroxyethyl methacrylate	HSR003005
CAS: 64-17-5	ethanol	HSR001144
CAS: 2867-47-2	2-dimethylaminoethyl methacrylate	HSR001558

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Warning

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

2-hydroxyethyl methacrylate

2-dimethylaminoethyl methacrylate

Bis-GMA

1,10-decandiol dimethacrylate

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methacrylated phosphoric acid ester

· **Hazard statements**

Flammable liquid and vapour.

May be harmful if inhaled.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

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

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.

If eye irritation persists: Get medical advice/attention.

· **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 the Directive 93/42/EEC.

· **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.

H227 Combustible liquid.

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.

H330 Fatal if inhaled.

H335 May cause respiratory irritation.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

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)

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

Flam. Liq. 4: Flammable liquids – Category 4

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 2: Acute toxicity – Category 2

Acute Tox. 5: Acute toxicity – Category 5

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

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

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

Skin Sens. 1: Skin sensitisation – Category 1

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