

# Safety Data Sheet

acc. to OSHA HCS

Printing date 04/20/2015




Version number 4

Reviewed on 03/11/2015

## 1 Identification

- **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 Inc.  
175 Pineview Drive, Amherst, N.Y. 14228  
USA  
Tel. +1 800 533 6825  
Fax +1 716 691 2285  
  
Ivoclar Vivadent Inc.  
1-6600 Dixie Road  
Mississauga, Ontario  
L5T 2Y2  
Canada  
Phone: +1 905 670 8499  
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**  
24 Hour Emergency Assistance:  
Emergency-Call USA - Infotrac: 1-800-535-5053  
Emergency-Call Canada - Canutec: 1-613-996-6666  
  
General SDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

## 2 Hazard(s) identification

- **Classification of the substance or mixture**  
Flam. Liq. 3 H226 Flammable liquid and vapour.  
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.  
Carc. 1A H350 May cause cancer.
- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**  
    
GHS02 GHS07 GHS08
- **Signal word** Danger
- **Hazard-determining components of labeling:**  
2-hydroxyethyl methacrylate

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Trade name: **Adhese Universal**

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ethanol

Bis-GMA

1,10-decandiol dimethacrylate

### · Hazard statements

Flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause cancer.

### · Precautionary statements

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

Avoid breathing dust/fume/gas/mist/vapors/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 are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

### · Classification system:

### · NFPA ratings (scale 0 - 4)



Health = 1

Fire = 3

Reactivity = 0

### · HMIS-ratings (scale 0 - 4)



Health = 1

Fire = 3

Reactivity = 0

### · 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 the substances listed below with nonhazardous additions.

### · Dangerous components:

868-77-9	2-hydroxyethyl methacrylate	20-<25%
1565-94-2	Bis-GMA	20-<25%
64-17-5	ethanol	10-<25%
6701-13-9	1,10-decandiol dimethacrylate	2.5-<10%
85590-00-7	Methacrylated phosphoric acid ester	2.5-<10%
10373-78-1	campherquinone	1-<2.5%
2867-47-2	2-dimethylaminoethyl methacrylate	1-<2.5%

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### 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.  
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:**  
CO<sub>2</sub>, extinguishing 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 protection against explosions and fires:**  
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.

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- **Further information about storage conditions:**  
Protect from exposure to the light.  
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

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

- **Control parameters**

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

#### 64-17-5 ethanol

PEL	Long-term value: 1900 mg/m <sup>3</sup> , 1000 ppm
REL	Long-term value: 1900 mg/m <sup>3</sup> , 1000 ppm
TLV	Short-term value: 1880 mg/m <sup>3</sup> , 1000 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.
- **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.
- **Breathing equipment:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **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

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### 9 Physical and chemical properties

**· Information on basic physical and chemical properties**
**· General Information**
**· Appearance:**
**Form:** Liquid

**Color:** Yellow

**· Odor:** 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 (97 °F) (ASTM D7094)

**· Auto igniting:** Product is not selfigniting.

**· Danger of explosion:** Product does not present an explosion hazard.

**· Explosion limits:**
**Lower:** Not determined.

**Upper:** Not determined.

**· Vapor 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.

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### 11 Toxicological information

- **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 internally approved calculation methods for preparations:

Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

64-17-5	ethanol	I
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability** No further relevant information available.

- **Behavior 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 (Self-assessment): hazardous for water

Do not allow product 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:**

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- **Uncleaned packagings:**

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

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### 14 Transport information

· UN-Number	
· DOT, ADR, IMDG, IATA	UN1170
· UN proper shipping name	
· DOT	Ethanol solutions
· ADR	1170 Ethanol solutions (Ethyl alcohol solutions)
· IMDG	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
· IATA	ETHANOL SOLUTION
· Transport hazard class(es)	
· DOT	
	
· Class	3 Flammable liquids
· Label	3
· ADR	
	
· Class	3 (F1) Flammable liquids
· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids
· Label	3
· Packing group	
· DOT, ADR, IMDG, IATA	III
· 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 MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml

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- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>· <b>IMDG</b></li> <li>· <b>Limited quantities (LQ)</b></li> <li>· <b>Excepted quantities (EQ)</b></li> </ul> | <p>5L<br/>Code: E1<br/>Maximum net quantity per inner packaging: 30 ml<br/>Maximum net quantity per outer packaging: 1000 ml</p> |
| <ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>  | <p>UN1170, Ethanol solutions (Ethyl alcohol solutions), 3, III</p>   |

### 15 Regulatory information

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

- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

64-17-5 ethanol

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

64-17-5 ethanol

A3

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS02   GHS07   GHS08

- **Signal word** Danger

- **Hazard-determining components of labeling:**

2-hydroxyethyl methacrylate

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ethanol

Bis-GMA

1,10-decandiol dimethacrylate

· **Hazard statements**

Flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause cancer.

· **Precautionary statements**

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

Avoid breathing dust/fume/gas/mist/vapors/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.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **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.

· **Date of preparation / last revision** 04/20/2015 / 3

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

Flam. Liq. 3: Flammable liquids, Hazard Category 3

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

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

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Carc. 1A: Carcinogenicity, Hazard Category 1A

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

- US