

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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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:**
CO₂, 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/m³, 1000 ppm

REL Long-term value: 1900 mg/m³, 1000 ppm

TLV Short-term value: 1880 mg/m³, 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 | 1 |

| |
|--|
| · 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

| | |
|---|---|
| <ul style="list-style-type: none"> · UN-Number · DOT, ADR, IMDG, IATA | <p style="margin: 0;">UN1170</p> |
| <ul style="list-style-type: none"> · UN proper shipping name · DOT · ADR · IMDG · IATA | <p style="margin: 0;">Ethanol solutions 1170 Ethanol solutions (Ethyl alcohol solutions) ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) ETHANOL SOLUTION</p> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT | <div style="text-align: center;">  </div> <p style="margin: 0;">3 Flammable liquids</p> |
| <ul style="list-style-type: none"> · Class · Label | <p style="margin: 0;">3</p> |
| <ul style="list-style-type: none"> · ADR | <div style="text-align: center;">  </div> <p style="margin: 0;">3 (F1) Flammable liquids</p> |
| <ul style="list-style-type: none"> · Class · Label | <p style="margin: 0;">3</p> |
| <ul style="list-style-type: none"> · IMDG, IATA | <div style="text-align: center;">  </div> <p style="margin: 0;">3 Flammable liquids</p> |
| <ul style="list-style-type: none"> · Class · Label | <p style="margin: 0;">3</p> |
| <ul style="list-style-type: none"> · Packing group · DOT, ADR, IMDG, IATA | <p style="margin: 0;">III</p> |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | <p style="margin: 0;">No</p> |
| <ul style="list-style-type: none"> · Special precautions for user · Danger code (Kemler): · EMS Number: | <p style="margin: 0;">Warning: Flammable liquids 30 F-E,S-D</p> |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | <p style="margin: 0;">Not applicable.</p> |
| <ul style="list-style-type: none"> · Transport/Additional information: | <p style="margin: 0;">Not applicable.</p> |
| <ul style="list-style-type: none"> · ADR · Excepted quantities (EQ) | <p style="margin: 0;">Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p> |

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- | | |
|--|--|
| <ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) | <p>5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p> |
| <ul style="list-style-type: none"> · UN "Model Regulation": | <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.**