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

(Contd. on page 2)
Trade name: **Adhese Universal**

40.1.5

- **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).

**Hazard description:**

- **WHMIS-symbols:**
  - B2 - Flammable liquid
  - D2B - Toxic material causing other toxic effects

**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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>% in mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>868-77-9 2-hydroxyethyl methacrylate</td>
<td>20-&lt;25%</td>
</tr>
<tr>
<td>1565-94-2 Bis-GMA</td>
<td>20-&lt;25%</td>
</tr>
<tr>
<td>64-17-5 ethanol</td>
<td>10-13%</td>
</tr>
<tr>
<td>6701-13-9 1,10-decandiol dimethacrylate</td>
<td>5-&lt;10%</td>
</tr>
</tbody>
</table>
**Trade name: Adhese Universal**

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Substance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>85590-00-7</td>
<td>Methacylated phosphoric acid ester</td>
<td>3-7%</td>
</tr>
<tr>
<td>10373-78-1</td>
<td>campherquinone</td>
<td>1-&lt;3%</td>
</tr>
<tr>
<td>2867-47-2</td>
<td>2-dimethylaminoethyl methacrylate</td>
<td>≤1%</td>
</tr>
</tbody>
</table>

### 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.
  - 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
    - EL: Short-term value: 1000 ppm
    - EV: Long-term value: 1.900 mg/m³, 1.000 ppm
- Additional information: The lists that were valid during the creation were used as basis.
- Exposure controls
- 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
9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Liquid
      - Color: Yellow
    - Odor:
      - 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 (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.
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.
## 14 Transport information

<table>
<thead>
<tr>
<th>DOT</th>
<th>UN Number</th>
<th>UN1170</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>DOT</td>
<td>Ethanol solutions</td>
</tr>
<tr>
<td>UN proper shipping name</td>
<td>TDG</td>
<td>1170 Ethanol solutions (Ethyl alcohol solutions)</td>
</tr>
<tr>
<td>UN proper shipping name</td>
<td>IMDG</td>
<td>ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)</td>
</tr>
<tr>
<td>UN proper shipping name</td>
<td>IATA</td>
<td>ETHANOL SOLUTION</td>
</tr>
</tbody>
</table>

- **Transport hazard class(es):**
  - **DOT:**
    - Class: 3 Flammable liquids
    - Label: 3
  - **TDG (Transport dangerous goods):**
    - Class: 3 (F1) Flammable liquids
    - Label: 3
  - **IMDG, IATA:**
    - Class: 3 Flammable liquids
    - Label: 3

- **Packing group:**
  - **DOT, TDG, IMDG, IATA:** III

- **Environmental hazards:**
  - Marine pollutant: No

- **Special precautions for user:**
  - Warning: Flammable liquids

- **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:**
  - **TDG**
    - Excepted quantities (EQ)
      - Code: E1
      - Maximum net quantity per inner packaging: 30 ml
      - Maximum net quantity per outer packaging: 1000 ml

(Contd. on page 8)
Trade name: Adhese Universal

<table>
<thead>
<tr>
<th>IMDG</th>
<th>Limited quantities (LQ)</th>
<th>5L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Excepted quantities (EQ)</td>
<td>Code: E1</td>
</tr>
<tr>
<td></td>
<td>Maximum net quantity per inner packaging: 30 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximum net quantity per outer packaging: 1000 ml</td>
<td></td>
</tr>
</tbody>
</table>

| UN "Model Regulation": | UN1993, Flammable liquids, n.o.s. (Ethanol (Ethyl alcohol)), 3, III |

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

(Contd. of page 9)
Material Safety Data Sheet
acc. to ISO 11014

Printing date 04/20/2015
Reviewed on 03/11/2015
Version number 4

Trade name: Adhese Universal

(Contd. of page 8)

· **Hazard-determining components of labeling:**
  2-hydroxyethyl methacrylate
  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:**
  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)
  WHMIS: Workplace Hazardous Materials Information System (Canada)
  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.*