This SDS packet was issued with item:
070363663

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070363655
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

· Signal word Danger

· Hazard-determining components of labeling:
  2-hydroxyethyl methacrylate

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

- **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.

<table>
<thead>
<tr>
<th>Dangerous components</th>
<th>Percentage</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-&lt;25%</td>
</tr>
<tr>
<td>6701-13-9 1,10-decandiol dimethacrylate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>85590-00-7 Methacrylated phosphoric acid ester</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>10373-78-1 camphorquinone</td>
<td>1-&lt;2.5%</td>
</tr>
<tr>
<td>2867-47-2 2-dimethylaminoethyl methacrylate</td>
<td>1-&lt;2.5%</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.
Trade name: **Adhese Universal**

- **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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>PEL Long-term value</th>
<th>REL Long-term value</th>
<th>TLV Short-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 ethanol</td>
<td>1900 mg/m³, 1000 ppm</td>
<td>1900 mg/m³, 1000 ppm</td>
<td>1880 mg/m³, 1000 ppm</td>
</tr>
</tbody>
</table>

- **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
### 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.

- **Partition coefficient (n-octanol/water):** Not determined.

- **Solubility in / Miscibility with Water:** Fully miscible.

- **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>ADR</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UN-Number</strong></td>
<td>UN1170</td>
<td>Ethanol solutions</td>
<td>Ethanol solutions (Ethyl alcohol solutions)</td>
</tr>
<tr>
<td><strong>DOT proper shipping name</strong></td>
<td>DOT Ethanol solutions</td>
<td>UN1170</td>
<td>ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)</td>
</tr>
<tr>
<td><strong>DOT</strong></td>
<td>DOT Ethanol solutions</td>
<td>UN1170</td>
<td>ETHANOL SOLUTION</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>3 Flammable liquids</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ADR</strong></td>
<td>3 (F1) Flammable liquids</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IMDG, IATA</strong></td>
<td>3 Flammable liquids</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Packing group</strong></td>
<td>DOT, ADR, IMDG, IATA</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td><strong>Environmental hazards:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Marine pollutant:</strong></td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Special precautions for user</strong></td>
<td>Warning: Flammable liquids</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Danger code (Kemler):</strong></td>
<td>30</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>EMS Number:</strong></td>
<td>F-E,S-D</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</strong></td>
<td>Not applicable.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 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

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

- 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": UN1170, Ethanol solutions (Ethyl alcohol solutions), 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
  - Hazard-determining components of labeling: 2-hydroxyethyl methacrylate
Trade name: Adhese Universal

ethanol
Bis-GMA
1,10-decanediol 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.