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**

- **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 vapor.
  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
  ethanol
  Bis-GMA

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

1,10-decandiol dimethacrylate
methacrylated phosphoric acid ester
2-dimethylaminoethyl methacrylate

Hazard statements
Flammable liquid and vapor.
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 = 2
Fire = 3
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = *2
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>CAS</th>
<th>Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>868-77-9</td>
<td>2-hydroxyethyl methacrylate</td>
<td>10-25%</td>
</tr>
<tr>
<td>36425-15-7</td>
<td>Bis-GMA</td>
<td>10-25%</td>
</tr>
<tr>
<td>64-17-5</td>
<td>ethanol</td>
<td>10-25%</td>
</tr>
<tr>
<td>6701-13-9</td>
<td>1,10-decandiol dimethacrylate</td>
<td>≥2.5-&lt;10%</td>
</tr>
<tr>
<td>85590-00-7</td>
<td>methacrylated phosphoric acid ester</td>
<td>≥2.5-&lt;10%</td>
</tr>
<tr>
<td>10373-78-1</td>
<td>camphorquinone</td>
<td>&lt;2.5%</td>
</tr>
<tr>
<td>2867-47-2</td>
<td>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 be sure to call 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:

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

  - 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

- Not suitable are gloves made of the following materials:
  - Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
### 9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Information</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Appearance</strong></td>
<td></td>
</tr>
<tr>
<td>Form</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>Characteristic</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>pH-value</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Change in condition</strong></td>
<td></td>
</tr>
<tr>
<td>Melting point/Melting range</td>
<td>Undetermined.</td>
</tr>
<tr>
<td>Boiling point/Boiling range</td>
<td>Undetermined.</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>36 °C (96.8 °F) (ASTM D7094)</td>
</tr>
<tr>
<td><strong>Auto igniting</strong></td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td><strong>Danger of explosion</strong></td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td><strong>Explosion limits</strong></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapor density</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with Water</strong></td>
<td>Fully miscible.</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water)</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td></td>
</tr>
<tr>
<td>Dynamic</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Kinematic</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

### 10 Stability and reactivity

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reactivity</strong></td>
<td>No further relevant information available.</td>
</tr>
<tr>
<td><strong>Chemical stability</strong></td>
<td>Stable under normal handling and storage conditions.</td>
</tr>
<tr>
<td><strong>Thermal decomposition / conditions to be avoided</strong></td>
<td>No decomposition if used according to specifications.</td>
</tr>
<tr>
<td><strong>Possibility of hazardous reactions</strong></td>
<td>No dangerous reactions known.</td>
</tr>
<tr>
<td><strong>Conditions to avoid</strong></td>
<td>Protect from exposure to the light.</td>
</tr>
<tr>
<td></td>
<td>Keep away from heat and direct sunlight.</td>
</tr>
<tr>
<td><strong>Incompatible materials</strong></td>
<td>No further relevant information available.</td>
</tr>
<tr>
<td><strong>Hazardous decomposition products</strong></td>
<td>None under normal conditions of storage and use.</td>
</tr>
</tbody>
</table>
11 Toxicological information

- Information on toxicological effects
  - Acute toxicity:
    - 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)
    CAS: 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

- UN-Number
  - DOT, ADR/RID/ADN, IMDG, IATA: UN1170

(Contd. on page 7)
Trade name: Adhese Universal

- UN proper shipping name
  - DOT Ethanol solutions
  - ADR/RID/ADN 1170 Ethanol solutions (Ethyl alcohol solutions)
  - IMDG ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
  - IATA ETHANOL SOLUTION

- Transport hazard class(es)
  - DOT 3 Flammable liquids
  - Label 3

- ADR/RID/ADN
  - Class 3 (F1) Flammable liquids
  - Label 3

- IMDG, IATA
  - Class 3 Flammable liquids
  - Label 3

- Packing group
  - DOT, ADR/RID/ADN, 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 MARPOL 73/78 and the IBC Code
  Not applicable.

- Transport/Additional information:

  - ADR/RID/ADN
    - Excepted quantities (EQ) Code: E1
    - Maximum net quantity per inner packaging: 30 ml
    - Maximum net quantity per outer packaging: 1000 ml

  - 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

(Contd. on page 8)
### 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:**
  - CAS: 64-17-5 ethanol

#### Carcinogenic categories

- **EPA (Environmental Protection Agency)**
  - None of the ingredients is listed.
- **TLV (Threshold Limit Value established by ACGIH)**
  - CAS: 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
- ethanol
- Bis-GMA
- 1,10-decandiol dimethacrylate
- methacrylated phosphoric acid ester
- 2-dimethylaminoethyl methacrylate
Trade name: Adhese Universal

- **Hazard statements**
  Flammable liquid and vapor.
  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.

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**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** 03/25/2019 / 4

- **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)
  NIOSH: National Institute for Occupational Safety
  OSHA: Occupational Safety & Health
  TLV: Threshold Limit Value
  PEL: Permissible Exposure Limit
  REL: Recommended Exposure Limit
  Flam. Liq. 3: Flammable liquids – Category 3
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
  Skin Sens. 1: Skin sensitisation – Category 1
  Carc. 1A: Carcinogenicity – Category 1A

- * Data compared to the previous version altered.