 SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1 Product identifier
  - Trade name: Adhese Universal

- 1.2 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

- 1.3 Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:
    Ivoclar Vivadent AG
    Bendererstrasse 2
    9494 Schaan
    PRINCIPALITY OF LIECHTENSTEIN
    
    Tel: +423 235 35 35
    Fax: +423 235 33 60

- 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

 SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
  - Classification according to Regulation (EC) No 1272/2008
    Flam. Liq. 3 H226 Flammable liquid and vapour.
    Skin Irrit. 2 H315 Causes skin irritation.
    Eye Irrit. 2 H319 Causes serious eye irritation.
    Skin Sens. 1 H317 May cause an allergic skin reaction.

- 2.2 Label elements
  - Labelling according to Regulation (EC) No 1272/2008
    The product is classified and labelled according to the CLP regulation.

- 2.3 Hazard pictograms
  - GHS02
  - GHS07

- Signal word Warning

- Hazard-determining components of labelling:
  - 2-hydroxyethyl methacrylate
  - Bis-GMA
  - 1,10-decanediol dimethacrylate
  - methacrylated phosphoric acid ester
  - 2-dimethylaminoethyl methacrylate

- Hazard statements
  - H226 Flammable liquid and vapour.
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  - H317 May cause an allergic skin reaction.
Precautionary statements

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards

Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Chemical Name</th>
<th>Hazard Class</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>868-77-9</td>
<td>212-782-2</td>
<td>2-hydroxyethyl methacrylate</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td>10-25%</td>
</tr>
<tr>
<td>36425-15-7</td>
<td>212-782-2</td>
<td>Bis-GMA</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td>10-25%</td>
</tr>
<tr>
<td>64-17-5</td>
<td>200-576-8</td>
<td>ethanol</td>
<td></td>
<td>10-25%</td>
</tr>
<tr>
<td>6701-13-9</td>
<td>229-745-1</td>
<td>1,10-decandiol dimethacrylate</td>
<td>Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td>≥2.5-&lt;10%</td>
</tr>
<tr>
<td>85590-00-7</td>
<td>229-745-1</td>
<td>methacrylated phosphoric acid ester</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td>≥2.5-&lt;10%</td>
</tr>
<tr>
<td>10373-78-1</td>
<td>229-745-1</td>
<td>camphorquinone</td>
<td></td>
<td>&lt;2.5%</td>
</tr>
<tr>
<td>2867-47-2</td>
<td>220-688-8</td>
<td>2-dimethylaminoethyl methacrylate</td>
<td>Acute Tox. 2, H330; Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td>≥1-&lt;2.5%</td>
</tr>
</tbody>
</table>

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 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.
 STYLE 7: Handling and storage

· 7.1 Precautions for safe handling
Only adequately trained personnel should handle this product.
For use in dentistry only.
Information about fire - and explosion protection:
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

· 7.2 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 container tightly sealed.

· 7.3 Specific end use(s) No further relevant information available.

* SECTION 8: Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.

(Contd. on page 4)
8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>CAS:</th>
<th>64-17-5 ethanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEL</td>
<td>Long-term value: 1920 mg/m³, 1000 ppm</td>
</tr>
</tbody>
</table>

Additional information: The lists valid during the making were used as basis.

8.2 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.

Respiratory protection:
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:
Form: Liquid
Colour: Yellow
Odour: Characteristic
Odour threshold: Not determined.

pH-value: Not applicable.

Change in condition
Melting point/freezing point: Undetermined.
Initial boiling point and boiling range: Undetermined.

Flash point: 36 °C (ASTM D7094)
**Trade name: Adhese Universal**

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Auto-ignition temperature</td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td>· Explosive properties</td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td>· Explosion limits</td>
<td></td>
</tr>
<tr>
<td>· Lower:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Upper:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Vapour pressure</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Density:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Vapour density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Evaporation rate</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Solubility in / Miscibility with water</td>
<td>Fully miscible.</td>
</tr>
<tr>
<td>· Partition coefficient: n-octanol/water</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Viscosity</td>
<td></td>
</tr>
<tr>
<td>· Dynamic:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Kinematic:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· 9.2 Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

**SECTION 10: Stability and reactivity**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>· 10.1 Reactivity</td>
<td>No further relevant information available.</td>
</tr>
<tr>
<td>· 10.2 Chemical stability</td>
<td>Stable under normal handling and storage conditions.</td>
</tr>
<tr>
<td>· Thermal decomposition / conditions to be avoided</td>
<td>No decomposition if used according to specifications.</td>
</tr>
<tr>
<td>· 10.3 Possibility of hazardous reactions</td>
<td>No dangerous reactions known.</td>
</tr>
<tr>
<td>· 10.4 Conditions to avoid</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>· 10.5 Incompatible materials</td>
<td>No further relevant information available.</td>
</tr>
<tr>
<td>· 10.6 Hazardous decomposition products</td>
<td>None under normal conditions of storage and use.</td>
</tr>
</tbody>
</table>

**SECTION 11: Toxicological information**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>· 11.1 Information on toxicological effects</td>
<td></td>
</tr>
<tr>
<td>· Acute toxicity</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>· Skin corrosion/irritation</td>
<td>Causes skin irritation.</td>
</tr>
<tr>
<td>· Serious eye damage/irritiation</td>
<td>Causes serious eye irritation.</td>
</tr>
<tr>
<td>· Respiratory or skin sensitisation</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>· Germ cell mutagenicity</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>· Carcinogenicity</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>· Reproductive toxicity</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>· STOT-single exposure</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>· STOT-repeated exposure</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>· Aspiration hazard</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
</tbody>
</table>
SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability: No further relevant information available.
- 12.3 Bioaccumulative potential: No further relevant information available.
- 12.4 Mobility in soil: No further relevant information available.
- Additional ecological information:
  - General notes:
    Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
    Do not allow product to reach ground water, water course or sewage system.
  - 12.5 Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.
- 12.6 Other adverse effects: No further relevant information available.

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
  - Recommendation
    Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
  - European waste catalogue
    18 01 06* chemicals consisting of or containing dangerous substances
  - Uncleaned packaging:
    - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR/RID/ADN, IMDG, IATA
    UN1170
- 14.2 UN proper shipping name
  - ADR/RID/ADN
    1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
  - IMDG
    ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
  - IATA
    ETHANOL SOLUTION
- 14.3 Transport hazard class(es)
  - ADR/RID/ADN
    - Class: 3 (F1) Flammable liquids.
    - Label: 3

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

- IMDG, IATA
- Class
  - Label 3 Flammable liquids.
- 14.4 Packing group
  - ADR/RID/ADN, IMDG, IATA III
- 14.5 Environmental hazards:
  - Marine pollutant: No
- 14.6 Special precautions for user
  - Warning: Flammable liquids.
  - Danger code (Kemler): 30
  - EMS Number: F-E,S-D
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
  - Not applicable.

- Transport/Additional information:
- ADR/RID/ADN
  - 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
- Transport category 3
- Tunnel restriction code D/E
- 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 SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III

* SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU
  - Qualifying quantity (tonnes) for the application of lower-tier requirements 5.000 t
  - Qualifying quantity (tonnes) for the application of upper-tier requirements 50.000 t
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- National regulations:
  - Other regulations, limitations and prohibitive regulations
    - The product is a medical device according to the Directive 93/42/EEC.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.
SECTION 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.

- Relevant phrases
  H225 Highly flammable liquid and vapour.
  H302 Harmful if swallowed.
  H312 Harmful in contact with skin.
  H315 Causes skin irritation.
  H317 May cause an allergic skin reaction.
  H319 Causes serious eye irritation.
  H330 Fatal if inhaled.
  H335 May cause respiratory irritation.

- Classification according to Regulation (EC) No 1272/2008
  The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

- 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
  IATA: International Air Transport Association
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  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)
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  Flam. Liq. 2: Flammable liquids – Category 2
  Flam. Liq. 3: Flammable liquids – Category 3
  Acute Tox. 4: Acute toxicity – Category 4
  Acute Tox. 2: Acute toxicity – Category 2
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  Skin Sens. 1: Skin sensitisation – Category 1
  STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.