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

1.1 Product identifier
Trade name: AdheSE Bonding

1.2 Relevant identified uses of the substance or mixture and uses advised against
Application of the substance / the mixture Light-curing, self-etching 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

Further information obtainable from:
Regulatory Affairs
sds@ivoclarvivadent.com

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
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.

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labelling:
Bis-GMA
2-hydroxyethyl methacrylate

Hazard statements
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves / eye protection / face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P321 Specific treatment (see on this label).

(Contd. on page 2)
**SECTION 3: Composition/information on ingredients**

3.2 Chemical characterisation: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**
  - CAS: 36425-15-7 Bis-GMA
    - Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317
    - 25-50%
  - CAS: 868-77-9 2-hydroxyethyl methacrylate
    - Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317
    - 10-25%

- **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.

- **After swallowing:**
  - Rinse out mouth and then drink plenty of water.
  - If symptoms persist consult doctor.

- **4.2 Most important symptoms and effects, both acute and delayed**
  - No further relevant information available.

- **4.3 Indication of any immediate medical attention and special treatment needed**
  - No further relevant information available.

**SECTION 5: Firefighting measures**

5.1 Extinguishing media

- **Suitable extinguishing agents:**
  - CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- **5.2 Special hazards arising from the substance or mixture**
  - No further relevant information available.

- **5.3 Advice for firefighters**
  - **Protective equipment:** No special measures required.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up:
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.

6.4 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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Only adequately trained personnel should handle this product.
For use in dentistry only.
Ensure good ventilation/exhaustion at the workplace.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:
Requirements to be met by storerooms and receptacles: No special requirements.
Information about storage in one common storage facility: Not required.
Further information about storage conditions:
Protect from exposure to the light.
Protect from heat and direct sunlight.
Keep container tightly sealed.

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Do not inhale gases / fumes / aerosols.
Respiratory protection: Not necessary if room is well-ventilated.
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

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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: Fluid
    - Colour: Yellowish
    - Odour: Characteristic
    - Odour threshold: Not determined.

  - pH-value: Not determined.

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

  - Flash point: Undetermined.
  - Auto-ignition temperature: Product is not selfigniting.

  - Explosive properties: Product does not present an explosion hazard.

  - Explosion limits:
    - Lower: Not determined.
    - Upper: Not determined.

  - Vapour pressure: Not determined.

  - Density at 20 °C: 1.135 g/cm³
  - Relative density: Not determined.
  - Vapour density: Not determined.
Trade name: AdheSE Bonding

- 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.

SECTION 10: Stability and reactivity

- 10.1 Reactivity: No further relevant information available.
- 10.2 Chemical stability: Stable under normal handling and storage conditions.
- 10.3 Possibility of hazardous reactions: No dangerous reactions known.
- 10.4 Conditions to avoid: Protect from exposure to the light. Keep away from heat and direct sunlight.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity: Based on available data, the classification criteria are not met.
  - Skin corrosion/irritation: Causes skin irritation.
  - Serious eye damage/irritation: Causes serious eye irritation.
  - Respiratory or skin sensitisation: May cause an allergic skin reaction.
  - Germ cell mutagenicity: Based on available data, the classification criteria are not met.
  - Carcinogenicity: Based on available data, the classification criteria are not met.
  - Reproductive toxicity: Based on available data, the classification criteria are not met.
  - STOT-single exposure: Based on available data, the classification criteria are not met.
  - STOT-repeated exposure: Based on available data, the classification criteria are not met.
  - Aspiration hazard: Based on available data, the classification criteria are not met.

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.
- Ecotoxical effects:
  - Remark: Harmful to fish
  - Additional ecological information:
    - General notes:
      Harmful to aquatic organisms

(Contd. on page 6)
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, ADN, IMDG, IATA Void

14.2 UN proper shipping name
ADR/RID/ADN, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
Class Void

14.4 Packing group
ADR/RID/ADN, IMDG, IATA Void

14.5 Environmental hazards:
Marine pollutant: No

14.6 Special precautions for user
Not applicable.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable.

Transport/Additional information: Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

UN "Model Regulation": Void

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
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
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.

- 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
  - 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

* Data compared to the previous version altered.