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

- **1.1 Product identifier**
  - **Trade name:** AdheSE Primer

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Ivoclar Vivadent AG
    Bendererstrasse 2
    FL-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, FL-9494 Schaan, Liechtenstein)

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**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - Classification according to Regulation (EC) No 1272/2008
    - **Skin Corr. 1B H314** Causes severe skin burns and eye damage.
    - **Eye Dam. 1 H318** Causes serious eye damage.
    - **Skin Sens. 1 H317** May cause an allergic skin reaction.
    - **STOT SE 3 H335** May cause respiratory irritation.

- **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**
  - GHS05
  - GHS07

- **Signal word** Danger

- **Hazard-determining components of labelling:**
  - phosphonic acid acrylate
  - bis-acrylamide derivative

- **Hazard statements**
  - H314 Causes severe skin burns and eye damage.
  - H317 May cause an allergic skin reaction.
  - H335 May cause respiratory irritation.

- **Precautionary statements**
  - **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/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.

(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:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>PCEC</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>223681-84-3 phosphonic acid acrylate</td>
<td>25-50%</td>
<td>Skin Corr. 1B, H314; Skin Sens. 1, H317</td>
</tr>
<tr>
<td>442200-41-1 bis-acrylamide derivative</td>
<td>10-&lt;25%</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335</td>
</tr>
</tbody>
</table>

**Additional information:** For the wording of the listed risk 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.
  Prevent formation of aerosols.
- **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

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
      - Keep away from foodstuffs, beverages and feed.
      - Immediately remove all soiled and contaminated clothing
      - Wash hands before breaks and at the end of work.
      - Avoid contact with the eyes and skin.
      - Do not inhale gases / fumes / aerosols.
    - 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

  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

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**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 applicable.

- **Change in condition**
  - Melting point/Melting range: Undetermined.
  - Boiling point/Boiling range: Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not applicable.

- **Self-igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

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

- **Vapour pressure:** Not determined.

- **Density at 20 °C:** 1.125 g/cm³

- **Relative density** Not determined.

- **Vapour density** Not determined.

(Contd. on page 5)
SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.
· 10.2 Chemical stability Stable under normal handling and storage conditions.
· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
· 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:
  · Primary irritant effect:
    · on the skin: Irritant to skin and mucous membranes.
    · on the eye: Irritating effect.
  · Sensitisation: Sensitisation possible through skin contact.
  · Additional toxicological information: No further relevant information available.

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 1 (German Regulation) (Self-assessment): slightly hazardous for water
  Do not allow undiluted product or large quantities of it 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, ADN, IMDG, IATA Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA Void

14.4 Packing group

ADR, 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 73/78 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": -

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory 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)
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

* Data compared to the previous version altered.