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

- **1.1 Product identifier**
  - **Trade name:** Helioseal Clear

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
  - Application of the substance / the mixture: Light-cured fissure sealant
  - No further relevant information available.

- **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.
    - **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.

- **2.3 Hazard pictograms**
  - ![Pictogram for Skin Irritation]
  - ![Pictogram for Eye Irritation]
  - ![Pictogram for Skin Sensitivity]
  - ![Pictogram for Respiratory Irritation]

- **Signal word** Warning

- **Hazard-determining components of labelling:**
  - Bis-GMA
  - triethylene glycol dimethacrylate

- **Hazard statements**
  - **H315** Causes skin irritation.
  - **H319** Causes serious eye irritation.
  - **H317** May cause an allergic skin reaction.
  - **H335** May cause respiratory irritation.

- **Precautionary statements**
  - **P261** Avoid breathing dust/fume/gas/mist/vapours/spray.
  - **P280** Wear protective gloves / eye protection / face protection.
  - **P304+P340** IF INHALED: Remove person to fresh air and keep comfortable for breathing.
Trade name: Helioseal Clear

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405 Store locked up.
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>NLP</th>
<th>Description</th>
<th>Hazard phrases</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>36425-15-7</td>
<td>500-089-0</td>
<td>Bis-GMA</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td>50-100%</td>
</tr>
<tr>
<td>109-16-0</td>
<td></td>
<td>triethyleneglycol dimethacrylate</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317, STOT SE 3, H335</td>
<td>25-50%</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.
After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
After swallowing: 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 Not required.
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.
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: 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.
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 and dental laboratories.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
Do not inhale gases / fumes / aerosols.
Respiratory protection: Not required.
Protection of hands:
Protective gloves
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

(Contd. on page 4)
Material of gloves
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: Safety glasses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:
Form: Fluid
Colour: Clear
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: Not applicable.

Flammability (solid, gas): Not applicable.

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: 1.12 g/cm³
Relative density
Vapour density Not determined.
Evaporation rate Not determined.

Solubility in / Miscibility with water: Nearly insoluble.
Partition coefficient: n-octanol/water: Not determined.

Viscosity:
Dynamic: Not determined.
Kinematic: Not determined.

9.2 Other information
No further relevant information available.

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(Contd. of page 3)
SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  Stable under normal handling and storage conditions.
  Photoreactive (Danger of polymerization).
- **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.
  - **Additional toxicological information** No further relevant information available.
  - **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** May cause respiratory irritation.
  - **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.
  - **Persistence and degradability** No further relevant information available.
  - **Bioaccumulative potential** No further relevant information available.
  - **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.
      Danger to drinking water if even small quantities leak into the ground.
    - **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.

- 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)
  - ADR/RID/ADN, ADN, IMDG, IATA: 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.
  - 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)
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
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
* Data compared to the previous version altered.