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

1.1 Product identifier

Trade name: Heliosit Orthodontic

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 bonding material for brackets

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.
Aquatic Chronic 3  H412 Harmful to aquatic life with long lasting effects.

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
urethane dimethacrylate
1,10-decandiol dimethacrylate
2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol

Hazard statements
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves / eye protection / face protection.

(Contd. on page 2)
Trade name: Heliosit Orthodontic

P302+P352 IF ON SKIN: Wash with plenty of water.  
P321 Specific treatment (see on this label).  
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/ EINECS</th>
<th>Substance</th>
<th>Skin Irrit.</th>
<th>Eye Irrit.</th>
<th>Skin Sens.</th>
<th>PBT</th>
<th>vPvB</th>
</tr>
</thead>
<tbody>
<tr>
<td>36425-15-7</td>
<td>Bis-GMA</td>
<td>H315</td>
<td>H319</td>
<td>H317</td>
<td></td>
<td></td>
</tr>
<tr>
<td>72869-86-4</td>
<td>urethane dimethacrylate</td>
<td>H319</td>
<td>H317</td>
<td>Aquatic Chronic 3, H412</td>
<td>20-&lt;25%</td>
<td></td>
</tr>
<tr>
<td>6701-13-9</td>
<td>1,10-decandiol dimethacrylate</td>
<td>10-25%</td>
<td>H317</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2440-22-4</td>
<td>2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol</td>
<td>Aquatic Chronic 1, H410; Skin Sens. 1, H317</td>
<td></td>
<td></td>
<td>20.25&lt;1%</td>
<td></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: 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.
Trade name: **Heliosit Orthodontic**

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: Pick up mechanically.
- 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.
- 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.
      - Avoid contact with the eyes and skin.
      - Keep away from foodstuffs, beverages and feed.
      - Respiratory protection: Not required.
      - Protection of hands:
        - Protective gloves

(Contd. on page 4)
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

- **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

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### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

  - **General Information**

    - **Appearance:**
      - Form: Pasty
      - Colour: According to product specification
    - **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.

  - **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:**
    - Not determined.
    - Relative density: Not determined.
    - 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.

(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.
  Photoreactive (Danger of polymerization).

- 10.3 Possibility of hazardous reactions
  No decomposition if used according to specifications.
  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
  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.

- 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.
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
Class

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.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

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
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

* Data compared to the previous version altered.