Safety Data Sheet
acc. to OSHA HCS

1 Identification

- **Product identifier**
  - **Trade name:** Heliosit Orthodontic

- **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

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**
    - Ivoclar Vivadent Inc.
      - 175 Pineview Drive, Amherst, N.Y. 14228
      - USA
      - Tel. +1 800 533 6825
      - Fax +1 716 691 2285
  - Ivoclar Vivadent Inc.
    - 1-6600 Dixie Road
    - Mississauga, Ontario
    - L5T 2Y2
    - Canada
    - Phone: +1 905 670 8499
    - Fax: +1 905 670 3102

  - **Information department:** Quality Assurance / Regulatory Affairs

  - **Emergency telephone number:**
    - 24 Hour Emergency Assistance:
      - Emergency-Call USA - Infotrac: 1-800-535-5053
      - Emergency-Call Canada - Canutec: 1-613-996-6666

    - General SDS Assistance:
      - US: 1-800-533-6825
      - Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
  - **Skin Irrit. 2 H315** Causes skin irritation.
  - **Eye Irrit. 2A H319** Causes serious eye irritation.
  - **Skin Sens. 1 H317** May cause an allergic skin reaction.

- **Label elements**
  - **GHS label elements**
    - The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**
  - GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**
  - Bis-GMA
  - urethane dimethacrylate
  - 1,10-decandiol dimethacrylate

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

- **Hazard statements**
  Causes skin irritation.
  Causes serious eye irritation.
  May cause an allergic skin reaction.
- **Precautionary statements**
  Wear protective gloves/protective clothing/eye protection/face protection.
  Wash contaminated clothing before reuse.
  If skin irritation or rash occurs: Get medical advice/attention.
  If eye irritation persists: Get medical advice/attention.
- **Additional information:**
  Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).
- **Classification system:**
  - **NFPA ratings (scale 0 - 4)**
    - Health = 1
    - Fire = 0
    - Reactivity = 0
  - **HMIS-ratings (scale 0 - 4)**
    - Health = 1
    - Fire = 0
    - Reactivity = 0
- **Other hazards**
  - Results of PBT and vPvB assessment
    - **PBT:** Not applicable.
    - **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

#### Dangerous components:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1565-94-2 Bis-GMA</td>
<td>50-100%</td>
</tr>
<tr>
<td>72869-86-4 urethane dimethacrylate</td>
<td>10-&lt;20%</td>
</tr>
<tr>
<td>6701-13-9 1,10-decandiol dimethacrylate</td>
<td>10-&lt;20%</td>
</tr>
</tbody>
</table>

### 4 First-aid measures

- **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.
- **Information for doctor:**
  **Most important symptoms and effects, both acute and delayed** No further relevant information available.
Trade name: Heliosit Orthodontic

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

5 Fire-fighting measures

- Extinguishing media
  - Suitable extinguishing agents:
    CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - Special hazards arising from the substance or mixture No further relevant information available.
  - Advice for firefighters
    - Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up: Pick up mechanically.
- 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.

7 Handling and storage

- Handling:
  - Precautions for safe handling
    Only adequately trained personnel should handle this product.
    For use in dentistry only.
  - Information about protection against explosions and fires: No special measures required.
- 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 receptacle tightly sealed.
- Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.
- Control parameters
  - Components 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 that were valid during the creation were used as basis.
Trade name: **Heliosit Orthodontic**

- **Exposure controls**
  - **Personal protective equipment:**
  - **General protective and hygienic measures:**
    Usual hygienic measures for dental practice.
    Wash hands before breaks and at the end of work.
    Avoid contact with the eyes and skin.
    Keep away from foodstuffs, beverages and feed.
  - **Breathing equipment:** 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
  - **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.
  - **Eye protection:** Safety glasses

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - **Form:** Pasty
    - **Color:** According to product specification
    - **Odor:** Characteristic
    - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.
  - **Change in condition**
    - **Melting point/Melting range:** Undetermined.
    - **Boiling point/Boiling range:** Undetermined.
  - **Flash point:** Not applicable.
  - **Auto igniting:** Product is not selfigniteing.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapor pressure:** Not determined.
  - **Density:** Not determined.
Trade name: **Heliosit Orthodontic**

- **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.
- **Other information**: No further relevant information available.

### 10 Stability and reactivity

- **Reactivity**: No further relevant information available.
- **Chemical stability**
  - Stable under normal handling and storage conditions.
  - Photoreactive (Danger of polymerization).
- **Thermal decomposition / conditions to be avoided**: No decomposition if used according to specifications.
- **Possibility of hazardous reactions**: No dangerous reactions known.
- **Conditions to avoid**
  - Protect from exposure to the light.
  - Keep away from heat and direct sunlight.
- **Incompatible materials**: No further relevant information available.
- **Hazardous decomposition products**: None under normal conditions of storage and use.

### 11 Toxicological information

- **Information on toxicological effects**
  - **Acute toxicity**:
  - **Primary irritant effect**:
    - on the skin: Irritant to skin and mucous membranes.
    - on the eye: Irritating effect.
  - **Sensitization**: Sensitization possible through skin contact.
  - **Additional toxicological information**: No further relevant information available.
- **Carcinogenic categories**
  - **IARC (International Agency for Research on Cancer)**
    - 7631-86-9 silicon dioxide, chemically prepared 3
  - **NTP (National Toxicology Program)**
    - None of the ingredients is listed.
  - **OSHA-Ca (Occupational Safety & Health Administration)**
    - None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
  - **Aquatic toxicity**: No further relevant information available.
  - **Persistence and degradability**: No further relevant information available.
40.1.5

- **Behavior in environmental systems:**
  - **Bioaccumulative potential** No further relevant information available.
  - **Mobility in soil** No further relevant information available.

- **Additional ecological information:**
  - **General notes:**
    Water hazard class 2 (Self-assessment): hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - **Results of PBT and vPvB assessment**
    - **PBT:** Not applicable.
    - **vPvB:** Not applicable.
  - **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
  - **Recommendation:**
    Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

<table>
<thead>
<tr>
<th>Item</th>
<th>DOT, ADR, ADN, IMDG, IATA</th>
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</tr>
</thead>
<tbody>
<tr>
<td>UN-Number</td>
<td>Void</td>
<td>Void</td>
<td>Void</td>
</tr>
<tr>
<td>UN proper shipping name</td>
<td>Void</td>
<td>Void</td>
<td>Void</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>Void</td>
<td>Void</td>
<td>Void</td>
</tr>
<tr>
<td>Environmental hazards:</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Marine pollutant:</td>
<td>Not applicable.</td>
<td>Not applicable.</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Special precautions for user</td>
<td>Not applicable.</td>
<td>Not applicable.</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</td>
<td>Not applicable.</td>
<td>Not applicable.</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport/Additional information:</td>
<td>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</td>
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<tr>
<td>UN &quot;Model Regulation&quot;:</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**
  - **Section 355 (extremely hazardous substances):** None of the ingredients is listed.
  - **Section 313 (Specific toxic chemical listings):** None of the ingredients is listed.
  - **TSCA (Toxic Substances Control Act):** All ingredients are listed.
- **Proposition 65**
  - **Chemicals known to cause cancer:** None of the ingredients is listed.
  - **Chemicals known to cause reproductive toxicity for females:** None of the ingredients is listed.
  - **Chemicals known to cause reproductive toxicity for males:** None of the ingredients is listed.
  - **Chemicals known to cause developmental toxicity:** None of the ingredients is listed.
- **Carcinogenic categories**
  - **EPA (Environmental Protection Agency)** None of the ingredients is listed.
  - **TLV (Threshold Limit Value established by ACGIH)** None of the ingredients is listed.
  - **NIOSH-Ca (National Institute for Occupational Safety and Health)** None of the ingredients is listed.
- **GHS label elements**
  - The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
  - GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**
  - Bis-GMA
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- **Hazard statements**
  - Causes skin irritation.
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  - May cause an allergic skin reaction.
- **Precautionary statements**
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - Wash contaminated clothing before reuse.
  - If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.

National regulations:

Other regulations, limitations and prohibitive regulations
The product is a medical device according to the Directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

Date of preparation / last revision: 04/20/2015 / 5

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
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

* Data compared to the previous version altered.