1 Identification

- **Product identifier**

- **Trade name:** Helioseal

- **Application of the substance / the mixture** Light-cured fissure sealant

- **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 identification

- **Classification of the substance or mixture**

  - **Skin Irritation - Category 2**
    - H315 Causes skin irritation.

  - **Eye Irritation - Category 2A**
    - H319 Causes serious eye irritation.

  - **Skin Sensitizer - Category 1**
    - H317 May cause an allergic skin reaction.

  - **Carcinogenicity – Category 2**
    - H351 Suspected of causing cancer.

  - **Specific Target Organ Toxicity - Single Exposure - Category 3**
    - H335 May cause respiratory irritation.

- **Label elements**

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

- **Hazard pictograms**

  - GHS07
  - GHS08

- **Signal word** Warning

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

(Contd. on page 2)
titanium dioxide
mequinol

**Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of causing cancer.
May cause respiratory irritation.

**Precautionary statements**
Obtain special instructions before use.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
Specific treatment (see on this label).
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF exposed or concerned: Get medical advice/attention.
Call a poison center/doctor if you feel unwell.

**Classification system:**

* **NFPA ratings (scale 0 - 4)**
  - Health = 2
  - Fire = 1
  - Reactivity = 0

* **HMIS-ratings (scale 0 - 4)**
  - Health = 2
  - Fire = 1
  - Reactivity = 0

**3 Composition/Information on ingredients**

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

**Dangerous components:**

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>36425-15-7</td>
<td>Bis-GMA</td>
<td>30-60% w/w *</td>
</tr>
<tr>
<td>109-16-0</td>
<td>triethylene glycol dimethacrylate</td>
<td>220-340% w/w *</td>
</tr>
<tr>
<td>13463-67-7</td>
<td>titanium dioxide</td>
<td>1-5% w/w *</td>
</tr>
</tbody>
</table>

(Contd. on page 3)
Trade name: Helioseal

CAS: 150-76-5 mequinol ≥ 0.1-<1% w/w *
* Actual concentration ranges are withheld as a trade secret.

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.
  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.
- Information for doctor:
  Most important symptoms and effects, both acute and delayed No further relevant information available.
  Indication of any immediate medical attention and special treatment needed
  No further relevant information available.

5 Firefighting 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:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Ensure adequate ventilation.
- 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.
**Trade name: Helioseal**

- **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.
- **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.
  - **Breathing equipment:**
    - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**

![Protective gloves]

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
After use of gloves apply skin-cleaning agents and skin cosmetics.
- **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

(Contd. on page 5)
9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Liquid
      - **Color:** White
    - **Odor:** Characteristic
    - **Odor threshold:** Not determined.
  - **pH-value:** Not applicable.
- **Change in condition**
  - **Melting point/Melting range:** Undetermined.
  - **Boiling point/Boiling range:** Undetermined.
- **Flash point:** Undetermined.
- **Flammability (solid, gaseous):** Not applicable.
- **Auto igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapor pressure:** Not determined.
  - **Density at 20 °C:** 1.14 g/cm³
  - **Relative density:** Not determined.
  - **Vapor 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.
  - Photoactive (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:
    - 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
  - NTP (National Toxicology Program)
    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.
  - 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 product 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**

- UN-Number
  - DOT, TDG, ADN, IMDG, IATA Void

- UN proper shipping name
  - DOT, TDG, ADN, IMDG, IATA Void

- Transport hazard class(es)
  - DOT, TDG, ADN, IMDG, IATA Class Void
Trade name: Helioseal

- Packing group: Void
- DOT, TDG, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user: Not applicable.
- 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": Void

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

![GHS07](image)
![GHS08](image)

- Signal word Warning
- Hazard-determining components of labeling:
  - Bis-GMA
  - triethylene glycol dimethacrylate
  - titanium dioxide
  - mequinol
- Hazard statements
  - Causes skin irritation.
  - Causes serious eye irritation.
  - May cause an allergic skin reaction.
  - Suspected of causing cancer.
  - May cause respiratory irritation.
- Precautionary statements
  - Obtain special instructions before use.
  - Do not handle until all safety precautions have been read and understood.
  - Avoid breathing dust/fume/gas/mist/vapours/spray.
  - Wash thoroughly after handling.
  - Use only outdoors or in a well-ventilated area.

(Contd. on page 8)
Contaminated work clothing should not be allowed out of the workplace. 
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
Specific treatment (see on this label).
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF exposed or concerned: Get medical advice/attention.
Call a poison center/doctor if you feel unwell.
Take off contaminated clothing and wash it before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

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 the latest revision of the safety data sheet 03/25/2019 / 7

Abbreviations and acronyms:
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.