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

1.1 Product identifier

Trade name: Helioseal F Plus

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 fissure sealant with fluoride release

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)

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.

2.3 Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labelling:
urethane dimethacrylate
Aromatic aliphatic urethane dimethacrylate

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/protective clothing/eye protection/face protection.
P273 Avoid release to the environment.
P264 Wash thoroughly after handling.

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Safety data sheet
according to 1907/2006/EC, Article 31

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Version number 1

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P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.

- 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>Description</th>
<th>Hazard Phrases</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>72869-86-4</td>
<td>urethane dimethacrylate</td>
<td>Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412</td>
<td>25-50%</td>
</tr>
<tr>
<td>276-957-5</td>
<td>EINECS: 72869-86-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>135843-75-0</td>
<td>2-Methacryloyloxy-ethyl phosphate</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>1219495-43-8</td>
<td>Aromatic aliphatic urethane dimethacrylate</td>
<td>Skin Sens. 1, H317</td>
<td>10-&lt;25%</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 or oxygen; call for 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. 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 Not required.

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**Safety data sheet**

*according to 1907/2006/EC, Article 31*

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**Trade name:** Helioseal F Plus

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### 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.

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

- Only adequately trained personnel should handle this product.
- For use in dentistry only.

#### 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.

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### SECTION 8: Exposure controls/personal protection

#### 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

- **General protective and hygienic measures:**
  - Usual hygienic measures for dental practice and dental laboratories.
  - Keep away from foodstuffs, beverages and feed.
  - Wash hands before breaks and at the end of work.
  - Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **Protection of hands:**

  ![Protective gloves](image)

  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

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(Contd. of page 4)
Trade name: Helioseal F Plus

- 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: White
    - Odour:
      - 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: Undetermined.
  - 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: 1.25 g/cm³
  - 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.
- 9.2 Other information
  No further relevant information available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity
  No further relevant information available.
- 10.2 Chemical stability
  Photoreactive (Danger of polymerization).
  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
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.

Persistence and degradability
No further relevant information available.

Bioaccumulative potential
No further relevant information available.

Mobility in soil
No further relevant information available.

Ecotoxicological effects:

Remark: Harmful to fish

Additional ecological information:

General notes:
Harmful to aquatic organisms
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product 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
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
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
  - Class
  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
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I None of the ingredients is listed.
  - 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.
  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
Trade name: Helioseal F Plus

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