

**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 09/29/2017

Version number 1

Reviewed on 09/29/2017


**1 Identification**

- **Product identifier**
- **Trade name: Helioseal F Plus**
- **Application of the substance / the mixture** Light-curing fissure sealant with fluoride release
- **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.

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  - **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:**  
urethane dimethacrylate
  - **Hazard statements**  
Causes skin irritation.  
Causes serious eye irritation.

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*May cause an allergic skin reaction.**Suspected of causing cancer.***· Precautionary statements***Avoid breathing dust/fume/gas/mist/vapours/spray.**Wear protective gloves/protective clothing/eye protection/face protection.**Avoid release to the environment.**Wash thoroughly after handling.**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

### 3 Composition/Information on ingredients

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

CAS: 72869-86-4	urethane dimethacrylate	30-60% w/w
CAS: 15458-75-0	2-Methacryloyloxy-ethyl phosphate	10-<25% w/w
CAS: 13463-67-7	titanium dioxide	0.1-≤1% w/w

### 4 First aid measures

**· 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.***· 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.*

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### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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.
- **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.  
Keep away from foodstuffs, beverages and feed.

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Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Breathing equipment:** Not required.

· **Protection of hands:**



Protective gloves

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

· **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

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

<b>Form:</b>	Fluid
<b>Color:</b>	White
<b>Odor:</b>	Characteristic
<b>Odor threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	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:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

· **Vapor pressure:** Not determined.

<b>Density at 20 °C:</b>	1.25 g/cm <sup>3</sup>
<b>Relative density</b>	Not determined.
<b>Vapor density</b>	Not determined.
<b>Evaporation rate</b>	Not determined.

· **Solubility in / Miscibility with**

**Water:** Nearly insoluble.

· **Partition coefficient (n-octanol/water):** Not determined.

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- **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**  
Photoreactive (Danger of polymerization).  
Stable under normal handling and storage conditions.
- **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**

- **IARC (International Agency for Research on Cancer)**

CAS: 13463-67-7 titanium dioxide

2B

- **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.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**  
Harmful to aquatic organisms  
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.

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- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
Must not be disposed of 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.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |  |
|--|--|
| · <b>UN-Number</b>   | Void   |
| · <b>DOT, TDG, ADN, IMDG, IATA</b>   | Void   |
| · <b>UN proper shipping name</b>   | Void   |
| · <b>DOT, TDG, ADN, IMDG, IATA</b>   | Void   |
| · <b>Transport hazard class(es)</b>  | Void   |
| · <b>DOT, TDG, ADN, IMDG, IATA</b>   | Void   |
| · <b>Class</b>   | Void   |
| · <b>Packing group</b>   | Void   |
| · <b>DOT, TDG, IMDG, IATA</b>  | Void   |
| · <b>Environmental hazards:</b>  | No   |
| · <b>Marine pollutant:</b>   | No   |
| · <b>Special precautions for user</b>  | Not applicable.  |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.  |
| · <b>Transport/Additional information:</b>                                       | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>  | 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).

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· **Hazard pictograms**

GHS07 GHS08

· **Signal word** *Warning*· **Hazard-determining components of labeling:***urethane dimethacrylate*· **Hazard statements***Causes skin irritation.**Causes serious eye irritation.**May cause an allergic skin reaction.**Suspected of causing cancer.*· **Precautionary statements***Avoid breathing dust/fume/gas/mist/vapours/spray.**Wear protective gloves/protective clothing/eye protection/face protection.**Avoid release to the environment.**Wash thoroughly after handling.**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** 09/29/2017 / -· **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*