

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 09/19/2013

Version number 6

Reviewed on 09/19/2013

**1 Identification**

- **Product identifier**
- **Trade name:** Variolink II (Base)
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation** Dual-curing/light-curing resin based dental luting material
- **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 MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

**2 Hazard(s) identification**

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Irritant  
Irritating to eyes. May cause sensitisation by skin contact.
  - **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- 
- **Label elements**
  - **Labelling according to EU guidelines:**  
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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
  - **Code letter and hazard designation of product:**



Irritant

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Trade name: **Variolink II (Base)**

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· **Hazard-determining components of labeling:**

triethyleneglycol dimethacrylate  
urethane dimethacrylate

· **Risk phrases:**

Irritating to eyes.  
May cause sensitisation by skin contact.

· **Safety phrases:**

Avoid contact with skin.  
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
Wear suitable gloves.  
This material and its container must be disposed of as hazardous waste.

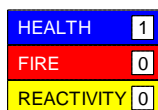
· **Classification system:**

· **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:**

1565-94-2	Bis-GMA	10-25%
72869-86-4	urethane dimethacrylate	2.5-10%
109-16-0	triethyleneglycol dimethacrylate	2.5-10%

### 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.

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

### 5 Fire-fighting 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:** 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.

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**Trade name: Variolink II (Base)**

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- **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

- |  |   |
|--|---|
| · <b>Information on basic physical and chemical properties</b> |   |
| · <b>General Information</b>                                   |   |
| · <b>Appearance:</b>   |   |
| <b>Form:</b>   | Pasty   |
| <b>Color:</b>  | According to product specification            |
| · <b>Odor:</b>   | Characteristic                                |
| · <b>Odour threshold:</b>                                      | Not determined.                               |
| · <b>pH-value:</b>   | Not applicable.                               |
| · <b>Change in condition</b>                                   |   |
| <b>Melting point/Melting range:</b>                            | Undetermined.                                 |
| <b>Boiling point/Boiling range:</b>                            | Undetermined.                                 |
| · <b>Flash point:</b>  | Not applicable.                               |
| · <b>Flammability (solid, gaseous):</b>                        | Not determined.                               |
| · <b>Auto igniting:</b>  | Product is not selfigniting.                  |
| · <b>Danger of explosion:</b>                                  | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                                     |   |
| <b>Lower:</b>  | Not determined.                               |
| <b>Upper:</b>  | Not determined.                               |

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· <b>Vapor pressure:</b>	<i>Not applicable.</i>
· <b>Density at 20 °C (68 °F):</b>	2.23 g/cm <sup>3</sup> (18.609 lbs/gal)
· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapour density</b>	<i>Not applicable.</i>
· <b>Evaporation rate</b>	<i>Not applicable.</i>
· <b>Solubility in / Miscibility with Water:</b>	<i>Nearly insoluble.</i>
· <b>Partition coefficient (n-octanol/water):</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
· <b>Dynamic:</b>	<i>Not applicable.</i>
· <b>Kinematic:</b>	<i>Not applicable.</i>
· <b>Other information</b>	<i>No further relevant information available.</i>

### 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:** *No irritant effect.*
- **on the eye:** *Irritating effect.*
- **Sensitization:** *Sensitization possible through skin contact.*
- **Additional toxicological information:**  
*The product shows the following dangers according to internally approved calculation methods for preparations:*  
*Irritant*
- **Carcinogenic categories**

· **NTP (National Toxicology Program)**

*None of the ingredients is listed.*

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*

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- **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 1 (Self-assessment): slightly 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

- |   |                 |
|---|-----------------|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> </ul>  | Void            |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void            |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void            |
| <ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>DOT, ADR, IMDG, IATA</b></li> </ul>   | Void            |
| <ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                     | No              |
| <ul style="list-style-type: none"> <li>· <b>Special precautions for user</b></li> </ul>   | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b></li> </ul>                        | Not applicable. |

### 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.*

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· **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)**

13760-80-0 ytterbium trifluoride

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Product related hazard informations:**

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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**



Irritant

· **Hazard-determining components of labeling:**

triethyleneglycol dimethacrylate  
urethane dimethacrylate

· **Risk phrases:**

Irritating to eyes.  
May cause sensitisation by skin contact.

· **Safety phrases:**

Avoid contact with skin.  
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
Wear suitable gloves.  
This material and its container must be disposed of as hazardous waste.

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- **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.*

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**1 Identification**

- **Product identifier**
- **Trade name:** Variolink II (Catalyst)
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation** Dual-curing/light-curing resin based dental luting material
- **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 MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

**2 Hazard(s) identification**

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Irritant  
Irritating to eyes and skin. May cause sensitisation by skin contact.
  - **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- 
- **Label elements**
  - **Labelling according to EU guidelines:**  
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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
  - **Code letter and hazard designation of product:**



Irritant

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Trade name: **Variolink II (Catalyst)**

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- **Hazard-determining components of labeling:**

triethyleneglycol dimethacrylate  
urethane dimethacrylate

- **Risk phrases:**

Irritating to eyes and skin.  
May cause sensitisation by skin contact.

- **Safety phrases:**

Avoid contact with skin.  
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
Wear suitable gloves.  
This material and its container must be disposed of as hazardous waste.

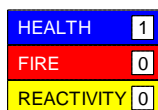
- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 1  
Fire = 0  
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



HEALTH 1 Health = 1  
FIRE 0 Fire = 0  
REACTIVITY 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:**

1565-94-2	Bis-GMA	50-100%
72869-86-4	urethane dimethacrylate	2.5-10%
109-16-0	triethyleneglycol dimethacrylate	2.5-10%
94-36-0	dibenzoyl peroxide	≤ 2.5%

### 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.

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**Trade name: Variolink II (Catalyst)**

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

### 5 Fire-fighting 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:** 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:**  
Store in a cool place.  
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.

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**Trade name: Variolink II (Catalyst)**

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- **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:**

<b>Form:</b>	Pasty
<b>Color:</b>	According to product specification
- **Odor:** Characteristic
- **Odour threshold:** 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:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.
- **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.

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Trade name: **Variolink II (Catalyst)**

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· <b>Vapor pressure:</b>	Not applicable.
· <b>Density at 20 °C (68 °F):</b>	2.23 g/cm <sup>3</sup> (18.609 lbs/gal)
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with Water:</b>	Nearly insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Dynamic:</b>	Not applicable.
· <b>Kinematic:</b>	Not applicable.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** 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:**
- **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:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant
- **Carcinogenic categories**

· <b>IARC (International Agency for Research on Cancer)</b>	
94-36-0	dibenzoyl peroxide
	3

· <b>NTP (National Toxicology Program)</b>	
None of the ingredients is listed.	

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.

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**Trade name: Variolink II (Catalyst)**

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- **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 1 (Self-assessment): slightly 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

- |   |                 |
|---|-----------------|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> </ul>  | Void            |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void            |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void            |
| <ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>DOT, ADR, IMDG, IATA</b></li> </ul>   | Void            |
| <ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                     | No              |
| <ul style="list-style-type: none"> <li>· <b>Special precautions for user</b></li> </ul>   | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b></li> </ul>                        | Not applicable. |

### 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.

(Contd. on page 7)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 09/19/2013

Version number 6

Reviewed on 09/19/2013

**Trade name: Variolink II (Catalyst)**

(Contd. of page 6)

· **Section 313 (Specific toxic chemical listings):**

94-36-0	dibenzoyl peroxide
---------	--------------------

· **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)**

13760-80-0	ytterbium trifluoride	A4
94-36-0	dibenzoyl peroxide	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Product related hazard informations:**

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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**



Irritant

· **Hazard-determining components of labeling:**

triethyleneglycol dimethacrylate  
urethane dimethacrylate

· **Risk phrases:**

Irritating to eyes and skin.  
May cause sensitisation by skin contact.

· **Safety phrases:**

Avoid contact with skin.  
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
Wear suitable gloves.  
This material and its container must be disposed of as hazardous waste.

(Contd. on page 8)

USA

**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 09/19/2013

Version number 6

Reviewed on 09/19/2013

**Trade name: Variolink II (Catalyst)**

(Contd. of page 7)

- **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.*

USA



**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 01/15/2015

Version number 5

Reviewed on 01/15/2015

**1 Identification**

- **Product identifier**
- **Trade name:** **Excite F DSC**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Dual-curing dental adhesive 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 MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

**2 Hazard(s) identification**

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Irritant  
Irritating to eyes and skin. May cause sensitisation by skin contact.  
Flammable.
  - **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- 
- **Label elements**
  - **Labelling according to EU guidelines:**  
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 Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
  - **Code letter and hazard designation of product:**



Irritant

(Contd. on page 2)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 01/15/2015

Version number 5

Reviewed on 01/15/2015

**Trade name: ExciTE F DSC**

(Contd. of page 1)

· **Hazard-determining components of labeling:**

2-hydroxyethyl methacrylate

· **Risk phrases:**

Flammable.

Irritating to eyes and skin.

May cause sensitisation by skin contact.

· **Safety phrases:**

Keep container tightly closed.

Keep away from sources of ignition - No smoking.

Do not breathe vapour/spray.

Avoid contact with skin.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 1

Fire = 3

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1

Fire = 3

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:**

1565-94-2	bisphenol A diglycidyl ether dimethacrylate	25-50%
64-17-5	ethanol	10-25%
868-77-9	2-hydroxyethyl methacrylate	10-25%
223681-84-3	phosphonic acid acrylate	10-25%
7789-23-3	potassium fluoride	≤ 2.5%

### 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:** Immediately rinse with water.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

(Contd. on page 3)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 01/15/2015

Version number 5

Reviewed on 01/15/2015

**Trade name: ExciTE F DSC**

(Contd. of page 2)

- **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 Fire-fighting 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.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** Cool endangered receptacles with water spray.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **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.  
Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **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.

(Contd. on page 4)

## Safety Data Sheet

### acc. to OSHA HCS

Printing date 01/15/2015

Version number 5

Reviewed on 01/15/2015

Trade name: **Excite F DSC**

(Contd. of page 3)

- **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:**

#### 64-17-5 ethanol

PEL	1900 mg/m <sup>3</sup> , 1000 ppm
REL	1900 mg/m <sup>3</sup> , 1000 ppm
TLV	Short-term value: 1880 mg/m <sup>3</sup> , 1000 ppm

- **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.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

- **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

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

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:**



Tightly sealed goggles

USA

(Contd. on page 5)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 01/15/2015

Version number 5

Reviewed on 01/15/2015

Trade name: **Excite F DSC**

(Contd. of page 4)

### 9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Fluid
Color:	Colorless
Odor:	Characteristic
Odour threshold:	Not determined.

· **pH-value (10 g/l) at 20 °C (68 °F):** 2.5

· **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· **Flash point:** 24 °C (75 °F)

· **Ignition temperature:** 425 °C (797 °F)

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

· **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

· **Vapor pressure at 20 °C (68 °F):** 59 hPa (44 mm Hg)

· **Density at 20 °C (68 °F):** 1.066 g/cm<sup>3</sup> (8.896 lbs/gal)

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

Water: Partly miscible.

· **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.

· **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.

USA

(Contd. on page 6)

## Safety Data Sheet acc. to OSHA HCS

Printing date 01/15/2015

Version number 5

Reviewed on 01/15/2015

Trade name: **ExciTE F DSC**

(Contd. of page 5)

### 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:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant
- **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.
- **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.

USA

(Contd. on page 7)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 01/15/2015




Version number 5

Reviewed on 01/15/2015

Trade name: **ExciTE F DSC**

(Contd. of page 6)

### 14 Transport information

<ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>	<p style="margin: 0;">UN1170</p> <p style="margin: 0;">1170</p>
<ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>ADR</b></li> <li>· <b>IMDG</b></li> <li>· <b>IATA</b></li> </ul>	<p style="margin: 0;">1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)</p> <p style="margin: 0;">ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)</p> <p style="margin: 0;">ETHANOL SOLUTION</p>
<ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>DOT</b></li> </ul>	<div style="text-align: center; margin: 10px 0;">  </div> <ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>
<ul style="list-style-type: none"> <li>· <b>ADR</b></li> </ul>	<div style="text-align: center; margin: 10px 0;">  </div> <ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>
<ul style="list-style-type: none"> <li>· <b>IMDG, IATA</b></li> </ul>	<div style="text-align: center; margin: 10px 0;">  </div> <ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>
<ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>DOT, ADR, IMDG, IATA</b></li> </ul>	<p style="margin: 0;">III</p>
<ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>	<p style="margin: 0;">No</p>
<ul style="list-style-type: none"> <li>· <b>Special precautions for user</b></li> <li>· <b>Danger code (Kemler):</b></li> <li>· <b>EMS Number:</b></li> </ul>	<p style="margin: 0;">Warning: Flammable liquids</p> <p style="margin: 0;">30</p> <p style="margin: 0;">F-E,S-E</p>
<ul style="list-style-type: none"> <li>· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b></li> </ul>	<p style="margin: 0;">Not applicable.</p>

USA

(Contd. on page 8)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 01/15/2015

Version number 5

Reviewed on 01/15/2015

Trade name: **Excite F DSC**

(Contd. of page 7)

### 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):**

1565-94-2	bisphenol A diglycidyl ether dimethacrylate
-----------	---

64-17-5	ethanol
---------	---------

868-77-9	2-hydroxyethyl methacrylate
----------	-----------------------------

7631-86-9	silicon dioxide, chemically prepared
-----------	--------------------------------------

7789-23-3	potassium fluoride
-----------	--------------------

· **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:**

64-17-5	ethanol
---------	---------

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

64-17-5	ethanol	
---------	---------	--

A3

7789-23-3	potassium fluoride	
-----------	--------------------	--

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **Product related hazard 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 Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**



Irritant

· **Hazard-determining components of labeling:**

2-hydroxyethyl methacrylate

(Contd. on page 9)



## Safety Data Sheet

acc. to OSHA HCS

Printing date 01/15/2015

Version number 5

Reviewed on 01/15/2015

**Trade name: ExciTE F DSC**

(Contd. of page 8)

**· Risk phrases:**

Flammable.  
Irritating to eyes and skin.  
May cause sensitisation by skin contact.

**· Safety phrases:**

Keep container tightly closed.  
Keep away from sources of ignition - No smoking.  
Do not breathe vapour/spray.  
Avoid contact with skin.  
Wear suitable gloves.  
This material and its container must be disposed of as hazardous waste.

**· 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** 01/15/2015 / 4
- **\* Data compared to the previous version altered.**

USA

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 05/21/2014

Version number 8

Reviewed on 05/20/2014

## 1 Identification

- **Product identifier**
- **Trade name:** **Total Etch**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Etching Gel
- **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 MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

## 2 Hazard(s) identification

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Corrosive  
Causes burns.
  - **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- 
- **Label elements**
  - **Labelling according to EU guidelines:**  
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 Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
  - **Code letter and hazard designation of product:**



Corrosive

(Contd. on page 2)

USA

## Safety Data Sheet

### acc. to OSHA HCS

Printing date 05/21/2014

Version number 8

Reviewed on 05/20/2014

**Trade name: Total Etch**

(Contd. of page 1)

· **Hazard-determining components of labeling:**

phosphoric acid

· **Risk phrases:**

Causes burns.

· **Safety phrases:**

When using do not eat or drink.

Do not breathe spray.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

This material and its container must be disposed of as hazardous waste.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 3

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 3

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:**

7664-38-2	phosphoric acid	25-50%
25322-68-3	Polyethylene glycol	2.5-<10%

### 4 First-aid measures

· **Description of first aid measures**

· **General information:** Immediately remove any clothing soiled by the product.

· **After inhalation:**

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

Immediately 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.

Do not induce vomiting; immediately call for medical help.

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 3)

## Safety Data Sheet acc. to OSHA HCS

Printing date 05/21/2014

Version number 8

Reviewed on 05/20/2014

**Trade name: Total Etch**

(Contd. of page 2)

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

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
The product is not flammable.  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dilute with plenty water.  
Use neutralizing agent.  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.
- **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

- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **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:**  
Keep receptacle tightly sealed.  
Protect from heat and direct sunlight.
- **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.

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## Safety Data Sheet

### acc. to OSHA HCS

Printing date 05/21/2014

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Reviewed on 05/20/2014

**Trade name: Total Etch**

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· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

**7664-38-2 phosphoric acid**

PEL	1 mg/m <sup>3</sup>
REL	Short-term value: 3 mg/m <sup>3</sup> Long-term value: 1 mg/m <sup>3</sup>
TLV	Short-term value: 3 mg/m <sup>3</sup> Long-term value: 1 mg/m <sup>3</sup>

**25322-68-3 Polyethylene glycol**

WEEL	10 mg/m <sup>3</sup> (H); MW>200
------	-------------------------------------

· **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.

Avoid contact with the eyes and skin.

Immediately remove all soiled and contaminated clothing.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

· **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.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

Butyl rubber, BR

Fluorocarbon rubber (Viton)

Nitrile rubber, NBR

Natural rubber, NR

Chloroprene rubber, CR

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:**



Tightly sealed goggles

USA

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## Safety Data Sheet

### acc. to OSHA HCS

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Trade name: **Total Etch**

(Contd. of page 4)

### 9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Viscous
Color:	Blue
Odor:	Odorless
Odour threshold:	Not determined.

· **pH-value at 20 °C (68 °F):** < 1

· **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:**

Decomposition temperature: Not determined.

· **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 (68 °F):** 1.29 g/cm<sup>3</sup> (10.765 lbs/gal)

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

Water: Soluble.

· **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.

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** None under normal conditions of storage and use.

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## Safety Data Sheet acc. to OSHA HCS

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Reviewed on 05/20/2014

Trade name: **Total Etch**

(Contd. of page 5)

### 11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

**7664-38-2 phosphoric acid**

Oral	LD50	1530 mg/kg (rat)
------	------	------------------

- **Primary irritant effect:**

- **on the skin:** Caustic effect on skin and mucous membranes.

- **on the eye:** Strong caustic effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Corrosive

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

- **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.

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

- **Additional ecological information:**

- **General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Must not reach bodies of water or drainage ditch undiluted or unneutralized.

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

- **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:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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**Trade name: Total Etch**

(Contd. of page 6)

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

### 14 Transport information

<ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT, ADR, IMDG, IATA</b></li> </ul>	UN1805
<ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT, IMDG, IATA</b></li> <li>· <b>ADR</b></li> </ul>	PHOSPHORIC ACID, SOLUTION 1805 PHOSPHORIC ACID, SOLUTION
<ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>DOT</b></li> </ul>	<div style="text-align: center;">  <p><b>CORROSIVE</b> 8</p> </div>
<ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>	8 Corrosive substances. 8
<ul style="list-style-type: none"> <li>· <b>ADR</b></li> </ul>	<div style="text-align: center;">  <p><b>8</b></p> </div>
<ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>	8 (C1) Corrosive substances 8
<ul style="list-style-type: none"> <li>· <b>IMDG, IATA</b></li> </ul>	<div style="text-align: center;">  <p><b>8</b></p> </div>
<ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>	8 Corrosive substances. 8
<ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>DOT, ADR, IMDG, IATA</b></li> </ul>	III
<ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>	No
<ul style="list-style-type: none"> <li>· <b>Special precautions for user</b></li> <li>· <b>Danger code (Kemler):</b></li> <li>· <b>EMS Number:</b></li> <li>· <b>Segregation groups</b></li> </ul>	Warning: Corrosive substances 80 F-A,S-B Acids
<ul style="list-style-type: none"> <li>· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b></li> </ul>	Not applicable.

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**Trade name: Total Etch**

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### 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):**

7664-38-2 phosphoric acid

· **TSCA (Toxic Substances Control Act):**

7732-18-5 water, distilled, conductivity or of similar purity

7664-38-2 phosphoric acid

· **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.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Product related hazard 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 Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**



Corrosive

· **Hazard-determining components of labeling:**

phosphoric acid

· **Risk phrases:**

Causes burns.

· **Safety phrases:**

When using do not eat or drink.

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**Trade name: Total Etch**

(Contd. of page 8)

*Do not breathe spray.*

*In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.*

*Wear suitable protective clothing, gloves and eye/face protection.*

*In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).*

*This material and its container must be disposed of as hazardous waste.*

· **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** 05/21/2014 / 7

· \* **Data compared to the previous version altered.**

USA

## 1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **Trade name:** **Monobond Plus**

· **Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

· **Application of the substance / the preparation**

Universal primer mediating a bond between metal, glass/oxid ceramics and resin

· **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 MSDS Assistance:

US: 1-800-533-6825

Canada: 1-800-263-8182

## 2 Hazards identification

· **Classification of the substance or mixture**

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**

Irritant

May cause sensitisation by skin contact.

Highly flammable

Highly flammable.

· **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**

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 Dangerous Substance Directive 1999/45/EWG usually if they are in the finished state and intended for the final user.

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USA

# Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/11/2012

Version number 6

Reviewed on 12/11/2012

Trade name: **Monobond Plus**

(Contd. of page 1)

· **Code letter and hazard designation of product:**



Irritant  
Highly flammable

· **Hazard-determining components of labelling:**

Methacrylated phosphoric acid ester

· **Risk phrases:**

Highly flammable.

May cause sensitisation by skin contact.

· **Safety phrases:**

Keep container tightly closed and in a well-ventilated place.

Keep away from sources of ignition - No smoking.

Do not breathe vapour/spray.

Avoid contact with skin.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 3

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 3

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:**

64-17-5	ethanol	50-100%
2530-85-0	3-trimethoxysilylpropyl methacrylate	≤ 2.5%
85590-00-7	Methacrylated phosphoric acid ester	≤ 2.5%

### 4 First aid measures

· **Description of first aid measures**

· **After inhalation:**

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

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## Safety Data Sheet acc. to ISO/DIS 11014

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Reviewed on 12/11/2012

**Trade name: Monobond Plus**

(Contd. of page 2)

- **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:** 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:**  
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.
- **Additional information** Cool endangered receptacles with water spray.

### 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.

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## Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/11/2012

Version number 6

Reviewed on 12/11/2012

**Trade name: Monobond Plus**

(Contd. of page 3)

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

**64-17-5 ethanol**

PEL	1900 mg/m <sup>3</sup> , 1000 ppm
REL	1900 mg/m <sup>3</sup> , 1000 ppm
TLV	Short-term value: 1880 mg/m <sup>3</sup> , 1000 ppm

· **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.  
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.

· **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>	Colorless
<b>Odor:</b>	Alcohol-like
<b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

**Melting point/Melting range:** -114.5 °C (-174 °F)

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Trade name: **Monobond Plus**

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<b>Boiling point/Boiling range:</b>	78 °C (172 °F)
· <b>Flash point:</b>	13 °C (55 °F)
· <b>Ignition temperature:</b>	425 °C (797 °F)
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· <b>Explosion limits:</b>	
<b>Lower:</b>	3.5 Vol %
<b>Upper:</b>	15 Vol %
· <b>Vapor pressure at 20 °C (68 °F):</b>	59 hPa (44 mm Hg)
· <b>Density at 20 °C (68 °F):</b>	0.794 g/cm <sup>3</sup> (6.626 lbs/gal)
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Soluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** 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** No further relevant information available.
- **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:**

#### · **LD/LC50 values that are relevant for classification:**

Oral	LD50	>5000 mg/kg (rat)
------	------	-------------------

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant

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USA

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Trade name: **Monobond Plus**

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· **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 1 (Self-assessment): slightly 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:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

### 14 Transport information

· **UN-Number**

· **DOT**

UN1170

· **ADR, IMDG, IATA**

1170

· **UN proper shipping name**

· **DOT, IATA**

ETHANOL, solution

· **ADR**

1170 ETHANOL (ETHYL ALCOHOL), solution

· **IMDG**

ETHANOL (ETHYL ALCOHOL), solution

· **Transport hazard class(es)**

· **DOT**



· **Class**

3 Flammable liquids.

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Trade name: **Monobond Plus**

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· <b>Label</b>	3
· <b>ADR</b>	
	
· <b>Class</b>	3 (F1) Flammable liquids
· <b>Label</b>	3

· **IMDG, IATA**

	
· <b>Class</b>	3 Flammable liquids.
· <b>Label</b>	3

· <b>Packing group</b>	
· <b>DOT, ADR, IMDG, IATA</b>	II

· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No

· <b>Special precautions for user</b>	Warning: Flammable liquids
· <b>Danger code (Kemler):</b>	33
· <b>EMS Number:</b>	F-E,S-D

· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
--	-----------------

### 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):**

64-17-5	ethanol
---------	---------

2530-85-0	3-trimethoxysilylpropyl methacrylate
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· **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.

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USA

## Safety Data Sheet

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Printing date 12/11/2012

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Reviewed on 12/11/2012

**Trade name: Monobond Plus**

(Contd. of page 7)

· **Chemicals known to cause developmental toxicity:**

64-17-5	ethanol
---------	---------

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

64-17-5	ethanol	
---------	---------	--

A3

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Product related hazard informations:**

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 Dangerous Substance Directive 1999/45/EWG usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**



Irritant  
Highly flammable

· **Hazard-determining components of labelling:**

Methacrylated phosphoric acid ester

· **Risk phrases:**

Highly flammable.

May cause sensitisation by skin contact.

· **Safety phrases:**

Keep container tightly closed and in a well-ventilated place.

Keep away from sources of ignition - No smoking.

Do not breathe vapour/spray.

Avoid contact with skin.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the EC-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.

· **\* Data compared to the previous version altered.**

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**1 Identification**

- **Product identifier**
- **Trade name:** ***Liquid Strip***
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation** Water-soluble glycerine paste
- **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 MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

**2 Hazard(s) identification**

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
  - **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- 
- **Label elements**
  - **Labelling according to EU guidelines:**  
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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
  - **Classification system:**
  - **NFPA ratings (scale 0 - 4)**



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· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	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:**

56-81-5	glycerol	50-100%
---------	----------	---------

### 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **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.  
· **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting 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:** Pick up mechanically.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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### 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:**

#### 56-81-5 glycerol

PEL	15* 5** mg/m <sup>3</sup> *total dust **respirable fraction
TLV	10* ppm *Mist

- **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.  
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:**  
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.

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- **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:**

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

- **pH-value:** Not determined.

- **Change in condition**

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

- **Flash point:** 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:</b>	Not determined.
<b>Relative density</b>	Not determined.
<b>Vapour density</b>	Not determined.
<b>Evaporation rate</b>	Not determined.

- **Solubility in / Miscibility with**

**Water:** Nearly insoluble.

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

- **Viscosity:**

<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	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.
- **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.

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- **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:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to internally approved calculation methods for preparations:  
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **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 1 (Self-assessment): slightly 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.

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### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>UN proper shipping name</b>   |                 |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>Transport hazard class(es)</b>  |                 |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>   | Void            |
| · <b>Packing group</b>   |                 |
| · <b>DOT, ADR, IMDG, IATA</b>  | Void            |
| · <b>Environmental hazards:</b>  |                 |
| · <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. |

### 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.

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**· OSHA-Ca (Occupational Safety & Health Administration)***None of the ingredients is listed.***· Product related hazard informations:***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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.***· 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.*

USA