

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

Printing date 03/25/2019

Version number 8

Reviewed on 03/21/2019

**1 Identification**

- **Product identifier**
- **Trade name:** **ExciTE F**
- **Application of the substance / the mixture** 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 SDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

**2 Hazard identification**

- **Classification of the substance or mixture**  
Flammable Liquids - Category 3    H226 Flammable liquid and vapour.  
Skin Corrosion - Category 1B      H314 Causes severe skin burns and eye damage.  
Serious Eye Damage - Category 1   H318 Causes serious eye damage.  
Skin Sensitizer - Category 1        H317 May cause an allergic skin reaction.  
Carcinogenicity - Category 1A      H350 May cause cancer.  
Reproductive Toxicity - Category 2 H361 Suspected of damaging fertility or the unborn child.

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

· **Hazard pictograms**



- **Signal word** Danger
- **Hazard-determining components of labeling:**  
phosphonic acid acrylate  
Bis-GMA

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ethanol

2-hydroxyethyl methacrylate

urethane dimethacrylate

· **Hazard statements**

*Flammable liquid and vapour.**Causes severe skin burns and eye damage.**May cause an allergic skin reaction.**May cause cancer.**Suspected of damaging fertility or the unborn child.*

· **Precautionary statements**

*Obtain special instructions before use.**Do not handle until all safety precautions have been read and understood.**Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.**Keep container tightly closed.**Ground and bond container and receiving equipment.**Use explosion-proof [electrical/ventilating/lighting] equipment.**Use non-sparking tools.**Take actions to prevent static discharges.**Do not breathe dust/fume/gas/mist/vapours/spray.**Wash thoroughly after handling.**Contaminated work clothing should not be allowed out of the workplace.**Wear protective gloves/protective clothing/eye protection/face protection.**IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.**IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].**IF INHALED: Remove person to fresh air and keep comfortable for breathing.**Immediately call a poison center/doctor.**IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**IF exposed or concerned: Get medical advice/attention.**Specific treatment (see on this label).**Take off contaminated clothing and wash it before reuse.**If skin irritation or rash occurs: Get medical advice/attention.**Wash contaminated clothing before reuse.**In case of fire: Use for extinction: CO<sub>2</sub>, powder or water spray.**Store in a well-ventilated place. Keep cool.**Store locked up.**Dispose of contents/container in accordance with local/regional/national/international regulations.*

· **Additional information:**

*Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).*

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 3

Fire = 3

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = \*3

Fire = 3

Reactivity = 0

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### 3 Composition/Information on ingredients

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

- **Dangerous components:**

CAS: 36425-15-7	Bis-GMA	15-40% w/w *
CAS: 64-17-5	ethanol	10-30% w/w *
CAS: 868-77-9	2-hydroxyethyl methacrylate	10-30% w/w *
CAS: 223681-84-3	phosphonic acid acrylate	7-13% w/w *
CAS: 72869-86-4	urethane dimethacrylate	≥5-<10% w/w *
CAS: 75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	0.1-1% w/w *

\* Actual concentration ranges are withheld as a trade secret.

### 4 First aid measures

- **Description of first aid measures**
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately rinse with water.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
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.

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- **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.
- **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:**

CAS: 64-17-5 ethanol

EL Short-term value: 1000 ppm

EV Long-term value: 1,900 mg/m<sup>3</sup>, 1,000 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 and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.  
Do not inhale gases / fumes / aerosols.
- **Breathing equipment:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

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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

## 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>	Characteristic
<b>Odor threshold:</b>	Not determined.

· **pH-value (10 g/l) at 20 °C:** 2.5

· **Change in condition**

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

· **Flash point:** 24 °C

· **Ignition temperature:** 425 °C

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

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

· **Explosion limits:**

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

· **Vapor pressure at 20 °C:** 59 hPa

<b>Density at 20 °C:</b>	1.066 g/cm <sup>3</sup>
<b>Relative density</b>	Not determined.
<b>Vapor density</b>	Not determined.
<b>Evaporation rate</b>	Not determined.

· **Solubility in / Miscibility with**

**Water:** Partly miscible.

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- **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.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
  - on the skin:** Irritant to skin and mucous membranes.
  - on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** No further relevant information available.
- **Carcinogenic categories**

#### · **NTP (National Toxicology Program)**

None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
  - Water hazard class 2 (Self-assessment): hazardous for water
  - Do not allow product to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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### 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, TDG, IMDG, IATA</b></li> </ul>   | <p style="margin-left: 20px;">UN1170</p>   |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT, IATA</b></li> <li>· <b>TDG</b></li> <li>· <b>IMDG</b></li> </ul>   | <p style="margin-left: 20px;">ETHANOL SOLUTION<br/>1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)<br/>ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)</p>                                    |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>DOT</b></li> </ul>   | <div style="margin-left: 20px;">  <p style="margin-left: 20px;">3 Flammable liquids</p> </div>      |
| <ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> <li>· <b>TDG (Transport dangerous goods):</b></li> </ul>                   | <div style="margin-left: 20px;">  <p style="margin-left: 20px;">3 (F1) Flammable liquids</p> </div> |
| <ul style="list-style-type: none"> <li>· <b>IMDG, IATA</b></li> </ul>   | <div style="margin-left: 20px;">  <p style="margin-left: 20px;">3 Flammable liquids</p> </div>      |
| <ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>  | <div style="margin-left: 20px;"> <p style="margin-left: 20px;">3 Flammable liquids</p> <p style="margin-left: 20px;">3</p> </div>  |
| <ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>DOT, TDG, IMDG, IATA</b></li> </ul>   | <p style="margin-left: 20px;">III</p>  |
| <ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>   | <p style="margin-left: 20px;">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-left: 20px;">Warning: Flammable liquids<br/>30<br/>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-left: 20px;">Not applicable.</p>  |

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· **Transport/Additional information:**

· **TDG**

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· **IMDG**

· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· **UN "Model Regulation":**

UN1170, ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III

### 15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

All ingredients are listed.

· **GHS label elements**

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

· **Hazard pictograms**



GHS02

GHS05

GHS07

GHS08

· **Signal word Danger**

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

phosphonic acid acrylate

Bis-GMA

ethanol

2-hydroxyethyl methacrylate

urethane dimethacrylate

· **Hazard statements**

Flammable liquid and vapour.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

May cause cancer.

Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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Keep container tightly closed.

Ground and bond container and receiving equipment.

Use explosion-proof [electrical/ventilating/lighting] equipment.

Use non-sparking tools.

Take actions to prevent static discharges.

Do not breathe dust/fume/gas/mist/vapours/spray.

Wash thoroughly after handling.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves/protective clothing/eye protection/face protection.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Immediately call a poison center/doctor.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

In case of fire: Use for extinction: CO<sub>2</sub>, powder or water spray.

Store in a well-ventilated place. Keep cool.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **National regulations:**

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

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

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

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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