

Safety Data Sheet
acc. to OSHA HCS

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(s) identification

- **Classification of the substance or mixture**
Flam. Liq. 3 H226 Flammable liquid and vapor.
Skin Corr. 1B H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Carc. 1A H350 May cause cancer.
Repr. 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**
- 



- GHS02
GHS05
GHS07
GHS08
- **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 vapor.

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**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Avoid breathing vapours.

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/shower.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

· **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

· **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:**

CAS: 36425-15-7	Bis-GMA	25-50%
CAS: 64-17-5	ethanol	10-25%
CAS: 868-77-9	2-hydroxyethyl methacrylate	10-25%
CAS: 223681-84-3	phosphonic acid acrylate	10-25%
CAS: 72869-86-4	urethane dimethacrylate	≥2.5-<10%
CAS: 75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	≥0.1-<2.5%

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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 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, 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.

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

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.

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· Eye protection:



Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Fluid
· Color:	Colorless
· Odor:	Characteristic
· Odor 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 (75.2 °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 (44.3 mm Hg)

· Density at 20 °C (68 °F): 1.066 g/cm³ (8.896 lbs/gal)

· Relative density: Not determined.

· Vapor 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.

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- **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.

- **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.

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14 Transport information

<ul style="list-style-type: none"> · UN-Number · DOT, ADR/RID/ADN, IMDG, IATA 	<p>UN1170</p>
<ul style="list-style-type: none"> · UN proper shipping name · ADR/RID/ADN · IMDG · IATA 	<p>1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) ETHANOL SOLUTION</p>
<ul style="list-style-type: none"> · Transport hazard class(es) · DOT 	<div style="text-align: center;">  </div> <p>3 Flammable liquids</p>
<ul style="list-style-type: none"> · Class · Label 	<p>3 3</p>
<ul style="list-style-type: none"> · ADR/RID/ADN 	<div style="text-align: center;">  </div> <p>3 (F1) Flammable liquids</p>
<ul style="list-style-type: none"> · Class · Label 	<p>3 3</p>
<ul style="list-style-type: none"> · IMDG, IATA 	<div style="text-align: center;">  </div> <p>3 Flammable liquids</p>
<ul style="list-style-type: none"> · Class · Label 	<p>3 3</p>
<ul style="list-style-type: none"> · Packing group · DOT, ADR/RID/ADN, IMDG, IATA 	<p>III</p>
<ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: 	<p>No</p>
<ul style="list-style-type: none"> · Special precautions for user · Danger code (Kemler): · EMS Number: 	<p>Warning: Flammable liquids 30 F-E,S-E</p>
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: 	
<ul style="list-style-type: none"> · ADR/RID/ADN · Excepted quantities (EQ) 	<p>Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) 	<p>5L</p>

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· **Exempted 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 solutions (Ethyl alcohol solutions), 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.

· **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:**

CAS: 64-17-5 | ethanol

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

CAS: 64-17-5 | ethanol

A3

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

None of the ingredients is 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

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urethane dimethacrylate

· **Hazard statements**

Flammable liquid and vapor.
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**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Avoid breathing vapours.
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/shower.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.

· **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** 03/25/2019 / 7

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Flam. Liq. 3: Flammable liquids – Category 3
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Care. 1A: Carcinogenicity – Category 1A
Repr. 2: Reproductive toxicity – Category 2

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