

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

Printing date 25.03.2019

Version number 8

Revision: 21.03.2019

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

- **1.1 Product identifier**
- **Trade name: ExciTE F**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Dental adhesive with fluoride release
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
-
- **Tel:** +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Flam. Liq. 3 H226 Flammable liquid and vapour.
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.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS02 GHS05 GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**
phosphonic acid acrylate
Bis-GMA
2-hydroxyethyl methacrylate
urethane dimethacrylate
- **Hazard statements**
H226 Flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe dusts or mists.

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- P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
 P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P310 Immediately call a POISON CENTER/doctor.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P321 Specific treatment (see on this label).
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 36425-15-7 NLP: 500-089-0	Bis-GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	25-50%
CAS: 64-17-5 EINECS: 200-578-6	ethanol Flam. Liq. 2, H225	10-25%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
CAS: 223681-84-3	phosphonic acid acrylate Skin Corr. 1B, H314; Skin Sens. 1, H317	10-25%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	≥2.5-<10%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	<2.5%
CAS: 7789-23-3 EINECS: 232-151-5	potassium fluoride Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331	<2.5%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **After inhalation:**

Supply fresh air 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.

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- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 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 fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **7.2 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 container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **8.1 Control parameters**

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

CAS: 64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 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.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **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

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Fluid

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· Colour:	Colourless
· Odour:	Characteristic
· Odour threshold:	Not determined.
· pH-value (10 g/l) at 20 °C:	2.5
· Change in condition	
· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	Undetermined.
· Flash point:	24 °C
· Ignition temperature:	425 °C
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits:	
· Lower:	Not determined.
· Upper:	Not determined.
· Vapour pressure at 20 °C:	59 hPa
· Density at 20 °C:	1.066 g/cm ³
· 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.
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.

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- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:** No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

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

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
 - **European waste catalogue**
- | | |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing dangerous substances |
|-----------|--|
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---------------------------------------|--|
| · 14.1 UN-Number | UN1170 |
| · ADR/RID/ADN, IMDG, IATA | |
| · 14.2 UN proper shipping name | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · ADR/RID/ADN | ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · IMDG | ETHANOL SOLUTION |
| · IATA | ETHANOL SOLUTION |

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· 14.3 Transport hazard class(es)

· ADR/RID/ADN



· Class 3 (F1) Flammable liquids.
· Label 3

· IMDG, IATA



· Class 3 Flammable liquids.
· Label 3

· 14.4 Packing group

· ADR/RID/ADN, IMDG, IATA III

· 14.5 Environmental hazards:

· Marine pollutant: No

· 14.6 Special precautions for user

Warning: Flammable liquids.
· Danger code (Kemler): 30

· EMS Number: F-E,S-E

· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

· Transport/Additional information:

· ADR/RID/ADN

· 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

· Transport category 3

· Tunnel restriction code D/E

· 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

* **SECTION 15: Regulatory information**

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

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

· National regulations:

· Other regulations, limitations and prohibitive regulations

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

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· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**

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

· **Relevant phrases**

H225 *Highly flammable liquid and vapour.*
 H301 *Toxic if swallowed.*
 H311 *Toxic in contact with skin.*
 H314 *Causes severe skin burns and eye damage.*
 H315 *Causes skin irritation.*
 H317 *May cause an allergic skin reaction.*
 H319 *Causes serious eye irritation.*
 H331 *Toxic if inhaled.*
 H361f *Suspected of damaging fertility.*
 H412 *Harmful to aquatic life with long lasting effects.*

· **Abbreviations and acronyms:**

ADR: *Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*
 IMDG: *International Maritime Code for Dangerous Goods*
 IATA: *International Air Transport Association*
 GHS: *Globally Harmonised System of Classification and Labelling of Chemicals*
 EINECS: *European Inventory of Existing Commercial Chemical Substances*
 ELINCS: *European List of Notified Chemical Substances*
 CAS: *Chemical Abstracts Service (division of the American Chemical Society)*
 PBT: *Persistent, Bioaccumulative and Toxic*
 vPvB: *very Persistent and very Bioaccumulative*
 Flam. Liq. 2: *Flammable liquids – Category 2*
 Flam. Liq. 3: *Flammable liquids – Category 3*
 Acute Tox. 3: *Acute toxicity – Category 3*
 Skin Corr. 1B: *Skin corrosion/irritation – Category 1B*
 Skin Irrit. 2: *Skin corrosion/irritation – Category 2*
 Eye Dam. 1: *Serious eye damage/eye irritation – Category 1*
 Eye Irrit. 2: *Serious eye damage/eye irritation – Category 2*
 Skin Sens. 1: *Skin sensitisation – Category 1*
 Repr. 2: *Reproductive toxicity – Category 2*
 Aquatic Chronic 3: *Hazardous to the aquatic environment - long-term aquatic hazard – Category 3*

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

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