Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 08.08.2024 *Version number 10 (replaces version 9)* *Revision: 08.08.2024*

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** Light-curing dental adhesive

· **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@ivoclar.com
· **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

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SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Flam. Liq. 2	H225 Highly 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.
Repr. 1B	H360 May damage fertility or the unborn child.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.

· **Hazard pictograms**



GHS02 GHS05 GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**
phosphonic acid acrylate
2-hydroxyethyl methacrylate
ethyl p-dimethylaminobenzoate
urethane dimethacrylate
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.

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H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261 Avoid breathing vapours.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

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

· **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6 Reg.nr.: 01-2119457610-43-xxxx	ethanol Flam. Liq. 2, H225; Eye Irrit. 2, H319	10-25%
CAS: 868-77-9 EINECS: 212-782-2 Reg.nr.: 01-2119490169-29-xxxx	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 Aquatic Chronic 2, H411; Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-<10%
CAS: 162881-26-7 ELINCS: 423-340-5	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide Skin Sens. 1A, H317; Aquatic Chronic 4, H413	1-<2.5%
CAS: 10287-53-3 EINECS: 233-634-3 Reg.nr.: 01-2120766020-67-XXXX	ethyl p-dimethylaminobenzoate Repr. 1B, H360; Aquatic Chronic 2, H411	0.3-<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.

If skin irritation continues, consult a doctor.

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· **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.
· **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

· **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

· **Regulatory information** WEL: EH40/2020
· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as 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.
· **Hand protection**



Protective gloves (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.
· **Material of gloves**
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Not suitable are gloves made of the following materials:**
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
· **Eye/face protection**



Tightly sealed goggles (EN 166)

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SECTION 9: Physical and chemical properties

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

· **Colour:**	Colourless
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.

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· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	21.5 °C (ISO 13736)
· **pH**	Not applicable.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Partly miscible.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density at 20 °C:**	1.066 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **9.2 Other information**	No further relevant information available.
· **Appearance:**	
· **Form:**	Fluid
· **Important information on protection of health and environment, and on safety.**	
· **Ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· **Change in condition**	
· **Evaporation rate**	Not determined.
· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Highly flammable liquid and vapour.
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

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SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 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.

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· **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 hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**		
CAS: 7789-23-3 potassium fluoride		
Oral	LD50	245 mg/kg (rat)

· **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
· **Serious eye damage/irritation**
Causes serious eye damage.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **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**
May damage fertility or the unborn child.
· **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.
· **Additional toxicological information:** No further relevant information available.
· **11.2 Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

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.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
· **12.7 Other adverse effects** 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.

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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.

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

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SECTION 14: Transport information

· **14.1 UN number or ID number**	
· **ADR/RID/ADN, IMDG, IATA**	UN2924
· **14.2 UN proper shipping name**	
· **ADR/RID/ADN**	2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL (ETHYL ALCOHOL), phosphonic acid acrylate)
· **IMDG**	FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL (ETHYL ALCOHOL), phosphonic acid acrylate)
· **IATA**	FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL, phosphonic acid acrylate)
· **14.3 Transport hazard class(es)**	
· **ADR/RID/ADN**	



· **Class**	3 (FC) Flammable liquids.
· **Label**	3+8
· **IMDG**	



· **Class**	3 Flammable liquids.
· **Label**	3/8
· **IATA**	



· **Class**	3 Flammable liquids.
· **Label**	3 (8)
· **14.4 Packing group**	
· **ADR/RID/ADN, IMDG, IATA**	II
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No

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· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Hazard identification number (Kemler code):**	338
· **EMS Number:**	F-E,S-C
· **Stowage Category**	B
· **Stowage Code**	SW2 Clear of living quarters.
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	
· **ADR/RID/ADN**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **Transport category**	2
· **Tunnel restriction code**	D/E
· **IMDG**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **UN "Model Regulation":**	UN 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL (ETHYL ALCOHOL), PHOSPHONIC ACID ACRYLATE), 3 (8), II

*
SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **Seveso category** P5c FLAMMABLE LIQUIDS
· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5000 t
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50000 t

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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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.

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H331 Toxic if inhaled.
H360 May damage fertility or the unborn child.
H411 Toxic to aquatic life with long lasting effects.
H413 May cause long lasting harmful effects to aquatic life.

· **Abbreviations and acronyms:**
IMO: International Maritime Organization
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
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
Skin Sens. 1A: Skin sensitisation – Category 1A
Repr. 1B: Reproductive toxicity – Category 1B
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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