

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

Printing date 19.09.2024


Version number 4 (replaces version 3)

Revision: 17.09.2024


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

- **1.1 Product identifier**
- **Trade name: *Fluor Protector S***
- **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** Protective varnish containing fluoride
- **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)

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.
Eye Irrit. 2 H319 Causes serious eye irritation.
 - **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



GHS07
- **Signal word** *Danger*
 - **Hazard statements**
H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
 - **Precautionary statements**
- | | |
|----------------|--|
| P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P241 | Use explosion-proof [electrical/ventilating/lighting] equipment. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. |
| 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. |
| P501 | Dispose of contents/container in accordance with local/regional/national/international regulations. |

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· **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 (GB 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 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	50-100%
CAS: 12125-01-8 EINECS: 235-185-9	ammonium fluoride Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331	1-<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**

· **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:** Rinse with water.

· **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.

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.

· **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:** Wear self-contained respiratory protective device.

· **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.

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- **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.
- **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:**
Store in a cool location.
Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from oxidising agents.
- **Further information about storage conditions:**
Store receptacle in a well ventilated area.
Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

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/m ³ , 1000 ppm |
- **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.
- **Recommended filter device for short term use:** Filter AX

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- **Hand protection**



Protective gloves (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.

- **Material of gloves**

Butyl rubber, BR

Fluorocarbon rubber (Viton)

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.

- **Eye/face protection** Safety glasses

SECTION 9: Physical and chemical properties

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

- **General Information**

· Colour:	Colourless
· Odour:	like peppermint
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	20 °C
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.

- **9.2 Other information**

- **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.

- **Solvent content:**

- **Organic solvents:**

58.7 %

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· Water:	14.7 %
· Solids content:	0.0 %
· 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

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** Reacts with oxidising agents.
- **10.4 Conditions to avoid** No further relevant information available.
- **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.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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.

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· **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**· **Additional ecological information:**· **General notes:**

Water hazard class 1 (German Regulation) (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.

* **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.* **SECTION 14: Transport information**· **14.1 UN number or ID number**· **ADR/RID/ADN, IMDG, IATA**

UN1170

· **14.2 UN proper shipping name**· **ADR/RID/ADN**

1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

· **IMDG**

ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

· **IATA**

ETHANOL SOLUTION

· **14.3 Transport hazard class(es)**· **ADR/RID/ADN**· **Class**

3 (F1) Flammable liquids.

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· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group	
· ADR/RID/ADN, IMDG, IATA	II
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	
· Hazard identification number (Kemler code):	Warning: Flammable liquids. 33
· EMS Number:	F-E,S-D
· 14.7 Maritime transport in bulk according to IMO instruments	
Not applicable.	
· Transport/Additional information:	
· ADR/RID/ADN	
· Limited quantities (LQ)	1L
· Transport category	2
· Tunnel restriction code	D/E
· UN "Model Regulation":	
UN1170, ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II	

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **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 the Directive 93/42/EEC.
- **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.
- H319 Causes serious eye irritation.
- H331 Toxic if inhaled.

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· **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)

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

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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

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