

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

Printing date 06.05.2015


Version number 3

Revision: 29.04.2015

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

- **1.1 Product identifier**
- **Trade name: *Fluor Protector N***
- **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
FL-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, FL-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.
- **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**
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- 
- GHS02
- **Signal word** *Danger*
- **Hazard statements**
H225 Highly flammable liquid and vapour.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
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.

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SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6	ethanol Flam. Liq. 2, H225	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 risk 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. If symptoms persist, 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.
- **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.

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See Section 13 for disposal information.

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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:**

Keep container tightly sealed.

Store receptacle in a well ventilated area.

· **7.3 Specific end use(s)** No further relevant information available.

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:**

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.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

· **Respiratory protection:**

Not required.

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

· **Protection of hands:**



Protective gloves

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

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- **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 protection:** Safety glasses

SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Fluid
Colour:	Colourless
· Odour:	like peppermint
· Odour threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

- **Flash point:** 20 °C

- **Flammability (solid, gaseous):** Not applicable.

- **Self-igniting:** Product is not selfigniting.

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

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapour pressure:** Not determined.

- **Density:** Not determined.

- **Relative density** Not determined.

- **Vapour density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with water:**

Fully 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** Reacts with oxidising agents.

- **10.4 Conditions to avoid** No further relevant information available.

- **10.5 Incompatible materials:** No further relevant information available.

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- **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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitisation:** No sensitising effects known.

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 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.
- **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, IMDG, IATA | |
| · 14.2 UN proper shipping name | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · ADR | |
| · IMDG | ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · IATA | ETHANOL SOLUTION |

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· 14.3 Transport hazard class(es)

· ADR



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

· IMDG, IATA



- Class 3 Flammable liquids.
· Label 3

· 14.4 Packing group

- ADR, IMDG, IATA II

· 14.5 Environmental hazards:

- Marine pollutant: No

· 14.6 Special precautions for user

- Warning: Flammable liquids.
· Danger code (Kemler): 33
· EMS Number: F-E,S-D

· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

· Transport/Additional information:

· ADR

- 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

· 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.

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H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

· 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)

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Acute Tox. 3: Acute toxicity, Hazard Category 3

· * Data compared to the previous version altered.

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