

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 05/19/2015

Version number 3

Reviewed on 04/29/2015


**1 Identification**

- **Product identifier**
- **Trade name:** ***Fluor Protector S***
- **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
- **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. 2 H225 Highly flammable liquid and vapor.  
Carc. 1A H350 May cause cancer.

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  - **Label elements**
  - **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
- 

GHS02



GHS08
- **Signal word** *Danger*
  - **Hazard-determining components of labeling:**  
*ethanol*
  - **Hazard statements**  
*Highly flammable liquid and vapor.*  
*May cause cancer.*

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· **Precautionary statements**

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

Keep container tightly closed.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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 = 0

Fire = 2

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 2

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:**

64-17-5	ethanol	50-100%
12125-01-8	ammonium fluoride	1-<2.5%

### 4 First-aid measures

· **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.

· **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.

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### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray.
- **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:** Wear self-contained respiratory protective device.
- **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.
- **Information about protection against explosions and fires:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **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 oxidizing agents.
- **Further information about storage conditions:**  
Keep receptacle tightly sealed.  
Store receptacle in a well ventilated area.
- **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.

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· **Control parameters**

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

**64-17-5 ethanol**

PEL Long-term value: 1900 mg/m<sup>3</sup>, 1000 ppm

REL Long-term value: 1900 mg/m<sup>3</sup>, 1000 ppm

TLV Short-term value: 1880 mg/m<sup>3</sup>, 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.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

· **Breathing equipment:**

Not required.

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.

· **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

· **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

### 9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

**Form:** Fluid

**Color:** Colorless

· **Odor:** 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 (68 °F)

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· <b>Flammability (solid, gaseous):</b>	Not applicable.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not determined.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Fully miscible.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>VOC content:</b>	58.7 %
· <b>Other information</b>	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** Reacts with oxidizing agents.
- **Conditions to avoid** No further relevant information available.
- **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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- **Carcinogenic categories**

#### · IARC (International Agency for Research on Cancer)

81-07-2 | 1,2-benzisothiazol-3(2H)-one 1,1-dioxide

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#### · NTP (National Toxicology Program)

None of the ingredients is listed.

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· **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 1 (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.
- **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.

### 14 Transport information

- |   |  |
|---|--|
| · <b>UN-Number</b>  |  |
| · <b>DOT, ADR, IMDG, IATA</b>   | UN1170   |
| · <b>UN proper shipping name</b>  |  |
| · <b>DOT, IATA</b>  | ETHANOL SOLUTION                               |
| · <b>ADR</b>  | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · <b>IMDG</b>   | ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)      |
| · <b>Transport hazard class(es)</b>   |  |
| · <b>DOT</b>  |  |
|  |  |
| · <b>Class</b>  | 3 Flammable liquids                            |

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

· IMDG, IATA



· Class	3 Flammable liquids
· Label	3

· Packing group

· DOT, ADR, IMDG, IATA II

· Environmental hazards:

· Marine pollutant: No

· Special precautions for user

Warning: Flammable liquids

· Danger code (Kemler):

33

· EMS Number:

F-E,S-D

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

Not applicable.

· UN "Model Regulation":

UN1170, Ethanol solutions (Ethyl alcohol solutions), 3, II

### 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):

81-07-2 | 1,2-benzisothiazol-3(2H)-one 1,1-dioxide

· 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.

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· **Chemicals known to cause developmental toxicity:**

64-17-5	ethanol
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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

64-17-5	ethanol	A3
12125-01-8	ammonium fluoride	A4

· **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    GHS08

· **Signal word Danger**

· **Hazard-determining components of labeling:**

ethanol

· **Hazard statements**

Highly flammable liquid and vapor.

May cause cancer.

· **Precautionary statements**

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

Keep container tightly closed.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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 05/19/2015 / 2**

· **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)

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VOC: Volatile Organic Compounds (USA, EU)  
Flam. Liq. 2: Flammable liquids, Hazard Category 2  
Carc. 1A: Carcinogenicity, Hazard Category 1A

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

US