

## Safety Data Sheet in accordance with HSNO

Printing date 18.10.2019



Version number 1

Revision: 18.10.2019

### 1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** ***Cervitec F***
- **Relevant identified uses of the substance or mixture and uses advised against**  
*No further relevant information available.*
- **Application of the substance / the mixture** *Protective dental varnish*
- **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*
- 
- **Importer:**  
*Ivoclar Vivadent Ltd  
12 Omega St, Rosedale, Auckland  
New Zealand  
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990*
- **Further information obtainable from:**  
*Regulatory Affairs  
sds@ivoclarvivadent.com*
- **Emergency telephone number:** *0800 764 766 (National Poison Centre - 24 hours / 7 days)*

### 2 Hazards identification

- **Classification of the substance or mixture**  
*Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Acute Tox. 3 H331 Toxic if inhaled.  
Aquatic Acute 3 H402 Harmful to aquatic life.*
- **Label elements**
- **GHS label elements**  
*The product is classified and labelled according to the Globally Harmonised System (GHS).*
- **Hazard pictograms**
- |   |   |
|---|---|
|  |  |
| GHS02   | GHS06   |
- **Signal word** *Danger*
- **Hazard-determining components of labelling:**  
*Cetylpyridinium chloride monohydrate  
ammonium fluoride*
- **Hazard statements**  
*Highly flammable liquid and vapour.  
Toxic if inhaled.  
Harmful to aquatic life.*
- **Precautionary statements**  
*Keep away from heat/sparks/open flames/hot surfaces. No smoking.  
Avoid breathing dust/fume/gas/mist/vapours/spray.  
IF INHALED: Remove person to fresh air and keep comfortable for breathing.*

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Store in a well-ventilated place. Keep container tightly closed.

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

· **Additional information:**

Cosmetics which fall under Regulation (EC) 1223/2009 are exempt from the labeling requirements of Directive 1999/45/EC and Regulation (EC) 1272/2008.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### 3 Composition/Information on ingredients

· **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: 6004-24-6	Cetylpyridinium chloride monohydrate Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 1, H330; Eye Dam. 1, H318; Aquatic Acute 1, H400; Skin Irrit. 2, H315; STOT SE 3, H335	0.25-<1%
CAS: 12125-01-8 EINECS: 235-185-9	ammonium 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.

### 4 First aid measures

· **Description of first aid measures**

· **After inhalation:**

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

Rinse with water.

Generally the product does not irritate the skin.

· **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.

· **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.

### 5 Fire fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **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:** No special measures required.

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· **Additional information** Cool endangered receptacles with water spray.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **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 fire - and explosion protection:**  
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:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

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

· **Control parameters**

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

CAS: 64-17-5 ethanol

WES Long-term value: 1880 mg/m<sup>3</sup>, 1000 ppm

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

· **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.

Wash hands before breaks and at the end of work.

Do not inhale gases / fumes / aerosols.

· **Respiratory protection:** Not required.

· **Protection of hands:** Not required.

· **Material of gloves -**

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- Penetration time of glove material -
- Eye protection: Not required.

### 9 Physical and chemical properties

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

##### · General Information

##### · Appearance:

Form:	Fluid
Colour:	Clear
Odour:	like peppermint
Odour threshold:	Not determined.

· pH-value: Not determined.

##### · Change in condition

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

· Flash point: 21 °C (ASTM D7094)

· Flammability (solid, gas): Not applicable.

· 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:	3.5 Vol %
Upper:	15.0 Vol %

· Vapour pressure at 20 °C: 59 hPa

· Density at 20 °C: 0.87 g/cm<sup>3</sup>

· 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.

· Other information: 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: No dangerous reactions known.
- Conditions to avoid: No further relevant information available.
- Incompatible materials: No further relevant information available.

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· **Hazardous decomposition products:** None under normal conditions of storage and use.

### 11 Toxicological information

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour 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 2 (German Regulation) (Self-assessment): hazardous for water  
 Do not allow product to reach ground water, water course or sewage system.  
 Danger to drinking water if even small quantities leak into the ground.*
- **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**  
*Must not be disposed together with household garbage. Do not allow product to reach sewage system.  
 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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### 14 Transport information

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>ADR/RID/ADN, IMDG, IATA</b></li> </ul>   | <p>UN1992</p>   |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>ADR/RID/ADN</b></li> </ul> | <p>1992 FLAMMABLE LIQUID, TOXIC, N.O.S.<br/>(ETHANOL (ETHYL ALCOHOL), Cetylpyridinium chloride monohydrate)</p> |
| <ul style="list-style-type: none"> <li>· <b>IMDG</b></li> </ul>  | <p>FLAMMABLE LIQUID, TOXIC, N.O.S. (ETHANOL (ETHYL ALCOHOL), CETYLPYRIDINIUM CHLORIDE MONOHYDRATE)</p>          |
| <ul style="list-style-type: none"> <li>· <b>IATA</b></li> </ul>  | <p>Flammable liquids, toxic, n.o.s. (Ethanol, Cetylpyridinium chloride monohydrate)</p>                         |

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

· **Class** 3 (FT1) Flammable liquids.  
 · **Label** 3+6.1

· **IMDG**

· **Class** 3 Flammable liquids.  
 · **Label** 3/6.1

· **IATA**

· **Class** 3 Flammable liquids.  
 · **Label** 3 (6.1)

· **Packing group**

· **ADR/RID/ADN, IMDG, IATA** II

· **Environmental hazards:** Not applicable.

· **Special precautions for user** Warning: Flammable liquids.

· **Danger code (Kemler):** 336

· **EMS Number:** F-E,S-D

· **Stowage Category** B

· **Stowage Code** SW2 Clear of living quarters.

· **Transport in bulk according to Annex II of Marpol and the IBC Code** 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 1992 FLAMMABLE LIQUID, TOXIC, N.O.S.  
 (ETHANOL (ETHYL ALCOHOL),  
 CETYLPYRIDINIUM CHLORIDE MONOHYDRATE),

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3 (6.1), II

### 15 Regulatory information

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

· **New Zealand Inventory of Chemicals**

CAS: 64-17-5	ethanol
CAS: 6004-24-6	Cetylpyridinium chloride monohydrate
CAS: 12125-01-8	ammonium fluoride

· **HSNO Approval numbers**

CAS: 64-17-5	ethanol	HSR001144
CAS: 6004-24-6	Cetylpyridinium chloride monohydrate	HSR004158
CAS: 12125-01-8	ammonium fluoride	HSR006705

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS02 GHS06

· **Signal word** Danger

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

Cetylpyridinium chloride monohydrate  
ammonium fluoride

· **Hazard statements**

Highly flammable liquid and vapour.

Toxic if inhaled.

Harmful to aquatic life.

· **Precautionary statements**

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

Avoid breathing dust/fume/gas/mist/vapours/spray.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Store in a well-ventilated place. Keep container tightly closed.

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

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category**

H2 ACUTE TOXIC

P5c FLAMMABLE LIQUIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a cosmetic according to Regulation (EC) 1223/2009.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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### 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.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

· **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

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

Acute Tox. 1: Acute toxicity – Category 1

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3