

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 25.04.2023

Version number 22

Revision: 25.04.2023

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

- **1.1 Product identifier**
- **Trade name:** *VOCO Profluorid Varnish*
- **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** *Dental varnish*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
- **Further information obtainable from:** *Scientific department tel. +49 (0)4721-719-0*
- **1.4 Emergency telephone number:** *Poison Control Center Mainz +49 (0)6131-19240*

SECTION 2: Hazards identification

- **2.2 Label elements**
- **Classification according to Regulation (EC) No 1272/2008**
Flam. Liq. 3 H226 Flammable liquid and vapour.
Acute Tox. 4 H302 Harmful if swallowed.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **Labelling according to Regulation (EC) No 1272/2008**
As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- **Hazard pictograms** *GHS02, GHS07*
- **Signal word** *Warning*
- **Hazard statements**
Flammable liquid and vapour.
Harmful if swallowed.
Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Ground and bond container and receiving equipment.
Use explosion-proof [electrical/ventilating/lighting] equipment.
Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards**
Material should only be used with extreme caution in individuals who may not have control over their swallowing reflex (e.g. pre-school children and the disabled).
Use only for intended scope of application
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

	<i>Harzderivat</i>	<i>Aquatic Chronic 3, H412</i>	<i>25-50%</i>
<i>CAS: 64-17-5</i> <i>EINECS: 200-578-6</i>	<i>ethanol</i>	<i>Flam. Liq. 2, H225</i>	<i>10-25%</i>

(Contd. on page 2)

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(Contd. of page 1)

CAS: 7681-49-4	sodium fluoride	Acute Tox. 3, H301	2.5-5%
EINECS: 231-667-8		Skin Irrit. 2, H315; Eye Irrit. 2, H319	

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:**
Swallowing of larger amounts can lead to nausea, vomiting and/or diarrhoea.
Call for a doctor immediately.
- **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:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters** No further relevant information available.

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:** Pick up mechanically.
- **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** For dental use only.
- **Information about fire - and explosion protection:** Keep ignition sources away - Do not smoke.
- **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:** Do not store together with acids.
- **Further information about storage conditions:**
See storage instructions on package
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**
- **Additional information about design of technical facilities:** No further data; see item 7.

(Contd. on page 3)

Safety data sheet
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Revision: 25.04.2023

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(Contd. of page 2)

· Ingredients with limit values that require monitoring at the workplace:
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CAS: 64-17-5 ethanol (10-25%)

WEL Long-term value: 1920 mg/m ³ , 1000 ppm
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- **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

- **Respiratory protection:** Not required.

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

- **Material of gloves:** Not applicable.

- **Penetration time of glove material:** Not applicable.

SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Fluid
Colour:	Colourless
Odour:	Fruit-like

- **pH-value:** Not determined.

- **Change in condition**

Melting point/freezing point:	Undetermined.
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Initial boiling point and boiling range:	Undetermined.
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- **Flash point:** 36 °C

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Density:** Not determined.

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

Not miscible or difficult to mix.

- **Viscosity:**

Dynamic:	Not determined.
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Kinematic:	Not determined.
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- **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**

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

- **10.3 Possibility of hazardous reactions** Contact with acids releases toxic gases.

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

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

- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

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(Contd. on page 4)

Safety data sheet
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Trade name: **VOCO Profluorid Varnish**

(Contd. of page 3)

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**

- **Acute toxicity**
Harmful if swallowed.

· **LD/LC50 values relevant for classification:**

CAS: 7681-49-4 sodium fluoride

Oral	LD50	52 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

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 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product 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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

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|---------------------------------------|------------------------------|
| · 14.1 UN-Number | |
| · ADR, IMDG, IATA | UN1170 |
| · 14.2 UN proper shipping name | |
| · ADR | 1170 ETHANOL (ETHYL ALCOHOL) |
| · IMDG | ETHANOL (ETHYL ALCOHOL) |

(Contd. on page 5)

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(Contd. of page 4)

· IATA	ETHANOL
· 14.3 Transport hazard class(es)	
· ADR, IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group	
· ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	30
· EMS Number:	F-E,S-D
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5L
· Transport category	3
· Tunnel restriction code	D/E
· UN "Model Regulation":	UN 1170 ETHANOL (ETHYL ALCOHOL), 3, III

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** 5,000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t

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.

- **Department issuing SDS:** Scientific department
- **Contact:** Tel.: +49 (0)4721-719-0
- **Abbreviations and acronyms:**
 - Flam. Liq. 2: Flammable liquids – Category 2
 - Flam. Liq. 3: Flammable liquids – Category 3
 - Acute Tox. 3: Acute toxicity – Category 3
 - Acute Tox. 4: Acute toxicity – Category 4
 - Skin Irrit. 2: Skin corrosion/irritation – Category 2
 - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 - Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3