

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

Printing date 08.09.2016

Version number 21

Revision: 08.09.2016

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

- **2.1 Classification of the substance or mixture**
- **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.
- **2.2 Label elements**
- **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*
- **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.
Avoid breathing vapours.
Wear protective gloves / eye protection.
Wear protective clothing.
IF SWALLOWED: Call a doctor if you feel unwell.
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:**

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

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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:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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

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

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- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.

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/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
- **Flash point:** 36 °C
- **Self-igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Density at 20 °C:** 1.02 g/cm³
- **Solubility in / Miscibility with water:** Not miscible or difficult to mix.
- **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**
- **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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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**

- **Acute toxicity**
Harmful if swallowed.

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

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.
- **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 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**
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

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

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· 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.
· Danger code (Kemler):	30
· EMS Number:	F-E,S-D
· Stowage Category	A
· 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
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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:**
 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)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic

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*vPvB: very Persistent and very Bioaccumulative**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***· * Data compared to the previous version altered.**

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