Reviewed on 09/09/2016

Printing date 09/09/2016

1 Identification

- · Product identifier
- · Trade name: VOCO Profluorid Varnish
- · Application of the substance / the mixture Dental varnish
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

VOCO GmbH

Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

- · Information department: Scientific department tel. +49 (0)4721-719-0
- · Emergency telephone number: Scientific department tel. +49 (0)4721-719-0

2 Hazard(s) identification

Health effects are based on the unmixed/uncured material.

Under FDA regulations this product is classified as a medical device.

Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

· Classification of the substance or mixture



Flame

Flam. Liq. 3 H226 Flammable liquid and vapor.



Acute Tox. 4 H302 Harmful if swallowed.

- · Label elements
- · Hazard pictograms GHS02, GHS07
- · Signal word Warning
- · Hazard statements

Flammable liquid and vapor.

Harmful if swallowed.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. 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.

· Other hazards

Material should only be used with extreme caution in individuals who may 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.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- \cdot **Description:** Mixture of the substances listed below with nonhazardous additions.
- · Dangerous components:

64-17-5 ethanol Flam. Liq. 2, H225 10-25%

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 7681-49-4
 sodium fluoride
 Acute Tox. 3, H301 Skin Irrit. 2, H315; Eye Irrit. 2, H319
 2.5-5%

4 First-aid measures

- · 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. Immediately call a 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:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters No further relevant information available.

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: Pick up mechanically.
- · 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 For dental use only.
- · Information about protection against explosions and fires: Keep ignition sources away Do not smoke.
- · 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 receptacle tightly sealed.

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

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8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components 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 that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- · Protection of hands: Not required.
- · Material of gloves Not required.

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Fluid
Color: Colorless
• Odor: Fruit-like

· pH-value: Not determined.

· Change in condition

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

• Flash point: $36 \, ^{\circ}C \, (97 \, ^{\circ}F)$

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

• **Density at 20 •C** (68 •F): $1.02 \text{ g/cm}^3 (8.512 \text{ lbs/gal})$

· Solubility in / Miscibility with

Water: Not miscible or difficult to mix.

· 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
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions Contact with acids releases toxic gases.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

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11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

7681-49-4 sodium fluoride

Oral LD50 52 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

The component 64-17-5 Ethanol is listed by IARC as Group 1 but in alcoholic beverages consumption only. This product is not an alcoholic beverage.

7681-49-4 sodium fluoride

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- $\cdot \textbf{\textit{Aquatic toxicity:}} \ \textit{No further relevant information available}.$
- $\cdot \textit{Persistence and degradability} \ \textit{No further relevant information available}.$
- · 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:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- Recommendation: Disposal must be made according to official regulations.

US

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4 Transport information	
· UN-Number · DOT, ADR, IMDG, IATA	UN1170
· UN proper shipping name · DOT · ADR · IMDG · IATA	Ethanol 1170 Ethanol ETHANOL (ETHYL ALCOHOL) ETHANOL
· Transport hazard class(es)	
\cdot DOT	
· Class	3 Flammable liquids
· Label	3
· ADR, IMDG, IATA · Class	3 Flammable liquids
· Label	3
· Packing group · DOT, ADR, IMDG, IATA	III
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids
· Danger code (Kemler): · EMS Number:	30 F-E,S-D
· Stowage Category	A A
· Transport in bulk according to Anno MARPOL73/78 and the IBC Code	ex II of Not applicable.
· UN "Model Regulation":	UN 1170 ETHANOL, 3, III

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 are listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients are listed.

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· Chemicals known to cause reproductive toxicity for females:

None of the ingredients are listed

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed

· Chemicals known to cause developmental toxicity:

64-17-5 ethanol

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients are listed

· TLV (Threshold Limit Value established by ACGIH)

 64-17-5
 ethanol
 A3

 7681-49-4
 sodium fluoride
 A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients are listed

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- · Hazard pictograms GHS02, GHS07
- · Signal word Warning
- · Hazard statements

Flammable liquid and vapor.

Harmful if swallowed.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. 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.

16 Other information

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

- · Department issuing SDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0
- · Date of preparation / last revision 09/09/2016 / 20
- · 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

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Safety Data Sheet acc. to OSHA HCS

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PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

* Data compared to the previous version altered.