

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

Printing date 03.05.2021

Version number 9

Revision: 03.05.2021

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

- **1.1 Product identifier**
- **Trade name:** *Bifluorid 10*
- **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. 2 H225 Highly flammable liquid and vapour.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H336 May cause drowsiness or dizziness.
- **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*
- **Signal word** *Danger*
- **Hazard statements**
Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause drowsiness or dizziness.
- **Precautionary statements**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Use explosion-proof [electrical/ventilating/lighting] equipment.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Store locked up.
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.*

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· Dangerous components:			
CAS: 141-78-6 EINECS: 205-500-4	ethyl acetate	Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336	50-100%
CAS: 9004-70-0	Cellulose nitrate with alcohol	Flam. Liq. 1, H224 Eye Irrit. 2, H319	10-25%
CAS: 105-68-0 EINECS: 203-322-1	isopentyl propionate	Flam. Liq. 3, H226	10-25%
CAS: 7681-49-4 EINECS: 231-667-8	sodium fluoride	Acute Tox. 3, H301 Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-5%
CAS: 84961-50-2 EINECS: 284-638-7	Clove oil	Asp. Tox. 1, H304 Eye Irrit. 2, H319; Skin Sens. 1, H317	≤2.5%

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. If symptoms persist, consult a doctor.
- **After swallowing:**
Swallowing of larger amounts can lead to nausea, vomiting and/or diarrhoea.
If symptoms persist consult doctor.
- **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, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
Do not flush with water or aqueous cleansing agents
- **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.

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- No special precautions are necessary if used correctly.
- Follow the instructions for use.
- Ensure good ventilation/exhaustion at the workplace.
- Prevent formation of aerosols.
- **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:** Not required.
- **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.
- **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.
- Avoid contact with the eyes.
- **Respiratory protection:** Not required.
- **Protection of hands:**
-  Protective gloves
- **Material of gloves**
- The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Fluid
Colour:	Whitish
· Odour:	Characteristic

- **pH-value:** Not determined.
- **Change in condition**

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

- **Flash point:** <10 °C

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· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Density:	Not determined.
· 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** No dangerous reactions known.
- **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.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

Oral	LD50	5,800 mg/kg (mouse)
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CAS: 141-78-6 ethyl acetate

Oral	LD50	5,620 mg/kg (rabbit)
Inhalative	LC50/4 h	1,600 mg/l (rat)

CAS: 7681-49-4 sodium fluoride

Oral	LD50	52 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation**
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **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**
May cause drowsiness or dizziness.
- **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.

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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 | UN1993 |
| · 14.2 UN proper shipping name | |
| · ADR | 1993 FLAMMABLE LIQUID, N.O.S. (ETHYL ACETATE, NITROCELLULOSE WITH ALCOHOL) |
| · IMDG, IATA | FLAMMABLE LIQUID, N.O.S. (ETHYL ACETATE, NITROCELLULOSE WITH ALCOHOL) |
| · 14.3 Transport hazard class(es) | |
| · ADR, IMDG, IATA | |
| |  |
| · Class | 3 Flammable liquids. |
| · Label | 3 |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | II |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Warning: Flammable liquids. |
| · Danger code (Kemler): | 33 |
| · EMS Number: | F-E,S-E |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

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· Transport/Additional information:**· ADR**

- | | |
|---------------------------|-----|
| · Limited quantities (LQ) | 1L |
| · Transport category | 2 |
| · Tunnel restriction code | D/E |

- | | |
|--------------------------|--|
| · UN "Model Regulation": | UN 1993 FLAMMABLE LIQUID, N.O.S. (ETHYL ACETATE, NITROCELLULOSE WITH ALCOHOL), 3, II |
|--------------------------|--|

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:
 - Flam. Liq. 1: Flammable liquids – Category 1
 - Flam. Liq. 2: Flammable liquids – Category 2
 - Flam. Liq. 3: Flammable liquids – Category 3
 - Acute Tox. 3: Acute toxicity - oral – Category 3
 - Skin Irrit. 2: Skin corrosion/irritation – Category 2
 - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 - Skin Sens. 1: Skin sensitisation – Category 1
 - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
 - Asp. Tox. 1: Aspiration hazard – Category 1

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