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1 Identification

- · Product identifier
- · Trade name: Bifluorid 5
- · 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

· Classification of the substance or mixture



Flame

Flam. Liq. 2 H225 Highly flammable liquid and vapor.



Eye Irrit. 2A H319 Causes serious eye irritation.

STOT SE 3 H336 May cause drowsiness or dizziness.

· Additional information:

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).

- · Label elements
- · Hazard pictograms GHS02, GHS07
- · Signal word Danger
- · Hazard-determining components of labeling:

ethyl acetate

· Hazard statements

Highly flammable liquid and vapor.

Causes serious eye irritation.

May cause drowsiness or dizziness.

· Precautionary statements

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

Wear protective gloves / eye protection.

Wear protective clothing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

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).

- Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

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3 Composition/information on ingredients

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

· Dangerous	· Dangerous components:		
141-78-6	ethyl acetate	Flam. Liq. 2, H225 Eye Irrit. 2A, H319; STOT SE 3, H336	50-100%
9004-70-0	Cellulose nitrate with alcohol	Flam. Liq. 1, H224 Eye Irrit. 2A, H319	10-25%
105-68-0	isopentyl propionate	Flam. Liq. 3, H226	10-25%
	Clove oil	Acute Tox. 3, H301 Asp. Tox. 1, H304 Eye Irrit. 2A, H319	<i>≤</i> 2,5%

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. 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.

- · 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, sand, extinguishing powder. Do not use water.
- · 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.

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:

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.

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7 Handling and storage

- · Handling:
- Precautions for safe handling

For dental use only.

Ensure good ventilation/exhaustion at the workplace.

- · 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: Not required.
- · Further information about storage conditions:

See storage instructions on package

Keep receptacle tightly sealed.

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

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.

Avoid contact with the eyes.

- · Breathing equipment: 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

9 Physical and chemical properties

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

Form: Fluid
Color: Whitish
Odor: Fruit-like

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined.

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	(Contd. of page 3)
Boiling point/Boiling range:	Undetermined.
· Flash point:	< 10 °C (< 50 °F)
· Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Density at 20 °C (68 °F):	0.95 g/cm³ (7.928 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.

· LD/LC50 values that are relevant for classification:

- · Chemical stability
- · 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.
- $\cdot \textit{Incompatible materials:} \ \textit{No further relevant information available}.$
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

Oral	LD50	5800 mg/kg (mouse)		
141-78-6	141-78-6 ethyl acetate			
Oral	LD50	5620 mg/kg (rabbit)		
Inhalative	LC50/4 h	1600 mg/l (rat)		

- · Primary irritant effect:
- on the skin: No irritant effect.
- · on the eye: Irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

The information below represents toxicological information associated with the individual components of the uncured product. Once properly mixed and/or cured, the product is safe for its intended use

_		
	fumed silica	3
7789-75-5	calcium fluoride	3
7681-49-4	sodium fluoride	3

· NTP (National Toxicology Program)

None of the ingredients is listed.

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· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability 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.

· UN-Number · DOT, ADR, IMDG, IATA	UN1993
	UN1993
· UN proper shipping name · DOT	Flammable liquids, n.o.s. (Ethyl acetate, Nitrocellulose wi alcohol)
· ADR	1993 Flammable liquids, n.o.s. (Ethyl acetate, Nitrocellulo with alcohol)
· IMDG	FLAMMABLE L IQUID, N.O.S. (ETHYL AC ETATA NITROCELLULOSE WITH ALCOHOL)
· IATA	Flammable liquid, n.o.s. (Ethyl acetate, Nitrocellulose wialcohol)
Transport hazard class(es)	
· DOT	
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· Class	3 Flammable liquids

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(Contd. of page 5) · Label 3 · ADR, IMDG, IATA · Class 3 Flammable liquids ·Label · Packing group · DOT, ADR, IMDG, IATA II· Environmental hazards: · Marine pollutant: No · Special precautions for user Warning: Flammable liquids · Danger code (Kemler): · EMS Number: F-E,S-E· Stowage Category · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable. UN 1993 FLAMMABLE LIQUIDS, N.O.S. (ETHYL ACETATE, · UN "Model Regulation": NITROCELLULOSE WITH ALCOHOL), 3, II

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):

Contact Voco for more information

All ingredients are listed.

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

None of the ingredients are listed.

· 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:

None of the ingredients are listed

- · Cancerogenity categories
- · EPA (Environmental Protection Agency)

None of the ingredients are listed

· TLV (Threshold Limit Value established by ACGIH)

7789-75-5calcium fluorideA47681-49-4sodium fluorideA4

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· 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 Danger
- · Hazard statements

Highly flammable liquid and vapor.

Causes serious eye irritation.

May cause drowsiness or dizziness.

· Precautionary statements

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

Wear protective gloves / eye protection.

Wear protective clothing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

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

16 Other information

- · Department issuing SDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0
- · Date of preparation / last revision: 10/09/2019 / 7
- · Abbreviations and acronyms:

 $ADR: Accord \ européen \ sur \ le \ {\it transport des marchandises dangereuses par Route (European \ Agreement \ concerning \ the \ International \ and \ a$

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

 $PEL: Permissible\ Exposure\ Limit$

REL: Recommended Exposure Limit

Flam. Liq. 1: Flammable liquids, Hazard Category 1

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Flam. Liq. 3: Flammable liquids, Hazard Category 3

Acute Tox. 3: Acute toxicity, Hazard Category 3

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

Asp. Tox. 1: Aspiration hazard, Hazard Category 1

* Data compared to the previous version altered.

US