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

Hazardous according to criteria of Australian Safety and Compensation Council

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:
  Australia contact and address:
  VOCO Australia Pty Ltd.
  Suite 406-408, 251 Oxford Street,
  Bondi Junction, NSW 2022
- Further information obtainable from: Australia 02 9369 1770
- Emergency telephone number: Australia: 131126

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.
  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
- Hazard statements
  Highly flammable liquid and vapour.
  Causes serious eye irritation.
  May cause drowsiness or dizziness.
- 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 IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  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.

(Contd. on page 2)
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.
- Ensure good ventilation/exhaustion at the workplace.
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according to 1907/2006/EC, Article 31

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(Contd. of page 2)

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.

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### 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

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### 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/Melting range:** Undetermined.
    - **Boiling point/Boiling range:** Undetermined.

  - **Flash point:** <10 °C

  - **Self-igniting:** Product is not selfigniting.

(Contd. on page 4)
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:

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<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td></td>
<td>LD50</td>
<td>5800 mg/kg (mouse)</td>
</tr>
<tr>
<td>141-78-6 ethyl acetate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>5620 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative</td>
<td>LC50/4 h</td>
<td>1600 mg/l (rat)</td>
</tr>
<tr>
<td>141-78-6 sodium fluoride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>52 mg/kg (rat)</td>
</tr>
</tbody>
</table>

  Primary irritant effect:
  Skin corrosion/irritation
  Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
  Skin sensitisation 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
  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.

SECTION 12: Ecological information

· 12.1 Toxicity
  Aquatic toxicity: No further relevant information available.
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- **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**
  - ADG, IMDG, IATA: UN1993
- **14.2 UN proper shipping name**
  - **ADG:** 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)**
  - ADG, IMDG, IATA
    - **Class:** 3 Flammable liquids.
    - **Label:** 3
- **14.4 Packing group**
  - **ADG, IMDG, IATA:** II
- **14.5 Environmental hazards:**
  - **Marine pollutant:** No
- **14.6 Special precautions for user**
  - **Danger code (Kemler):** Warning: Flammable liquids.
    33
  - **EMS Number:** F-E,S-E
  - **Stowage Category:** B
- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**
  - **Not applicable.**
- **Transport/Additional information:**
  - **ADG**
  - **Limited quantities (LQ):** 1L

(Contd. on page 6)
**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Australian Inventory of Chemical Substances**
    - All ingredients are listed.
  - **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:**
  - 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
  - vPvB: very Persistent and very Bioaccumulative
  - 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 – 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
  - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
  - Asp. Tox. 1: Aspiration hazard – Category 1

* Data compared to the previous version altered.*