

SAFETY DATA SHEETS

This SDS packet was issued with item:

077109432

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

077109457

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077109440

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 08/30/2010

Reviewed on 08/30/2010

1 Identification of substance



- **Product details**
- **Trade name:** Profluorid L
- **Application of the substance / the preparation** Dental varnish
- **Manufacturer/Supplier:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
- **Information department:** Scientific department tel. +49 (0)4721-719-0
- **Emergency information:** Scientific department tel. +49 (0)4721-719-0

2 Composition/Data on components

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

· Dangerous components:		
141-78-6	ethyl acetate	50-100%
9004-70-0	Cellulose nitrate with alcohol	10-25%
105-68-0	isopentyl propionate	10-25%
7681-49-4	sodium fluoride	2.5-5%
	Clove oil	≤ 2.5%

3 Hazards identification

- **Hazard description:**
Highly flammable
- **Information pertaining to particular dangers for man and environment:**
The product has to be labelled due to the calculation procedure of international guidelines.
Highly flammable.
Contact with acids liberates toxic gas.
Vapours may cause drowsiness and dizziness.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **NFPA ratings (scale 0 - 4)**

Health = 0
Fire = 3
Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**

Health = 0
Fire = 3
Reactivity = 0
- **Additional information:**
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).

4 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.

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If symptoms persist consult doctor.

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5 Fire fighting measures

- **Suitable extinguishing agents:** CO₂, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Person-related safety precautions:** Wear protective equipment. Keep unprotected persons away.
- **Measures for environmental protection:** Do not allow to enter sewers/ surface or ground water.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
Do not flush with water or aqueous cleansing agents

7 Handling and storage

- **Handling:**
- **Information for safe handling:**
For dental use only.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** Keep ignition sources away - Do not smoke.
- **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.

8 Exposure controls and personal protection

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

- **Components with limit values that require monitoring at the workplace:**

141-78-6 ethyl acetate

PEL 1400 mg/m³, 400 ppmREL 1400 mg/m³, 400 ppmTLV 1440 mg/m³, 400 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

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Trade name: Profluorid L

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- 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.

- Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- Eye protection: Safety glasses

9 Physical and chemical properties

- General Information

Form:	Fluid
Color:	Whitish
Odor:	Characteristic

- Change in condition

Melting point/Melting range: Undetermined.

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): 1.01 g/cm³

- Solubility in / Miscibility with Water: Not miscible or difficult to mix.

10 Stability and reactivity

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

- Dangerous reactions No dangerous reactions known.

- Dangerous products of decomposition: No dangerous decomposition products known.

11 Toxicological information

- Acute toxicity:

- LD/LC50 values that are relevant for classification:

Oral	LD50	5800 mg/kg (mouse)
------	------	--------------------

141-78-6 ethyl acetate

Oral	LD50	5620 mg/kg (rabbit)
------	------	---------------------

Inhalative	LC50/4 h	1600 mg/l (rat)
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7681-49-4 sodium fluoride

Oral	LD50	52 mg/kg (rat)
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- Primary irritant effect:

- on the skin: No irritant effect.

- on the eye: Irritating effect.

- Sensitization: No sensitizing effects known.

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Trade name: Profluorid L

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Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

12 Ecological information

Additional ecological information:

General notes:

Water hazard class I (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.

13 Disposal considerations

Product:

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.

14 Transport information

DOT regulations:



Hazard class: 3

Identification number: UN1993

Packing group: II

Proper shipping name (technical name): FLAMMABLE LIQUID, N.O.S. (ETHYL ACETATE, NITROCELLULOSE WITH ALCOHOL)

Label: 3

Land transport ADR/RID (cross-border):



ADR/RID class: 3 Flammable liquids

Danger code (Kemler): 33

UN-Number: 1993

Packaging group: II

Label: 3

Description of goods: 1993 FLAMMABLE LIQUID, N.O.S. (ETHYL ACETATE, NITROCELLULOSE WITH ALCOHOL)

Maritime transport IMDG:



IMDG Class: 3

UN Number: 1993

Label: 3

Packaging group: II

EMS Number: F-E-S-E

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Trade name: Profluorid L

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· Marine pollutant: No
 · Proper shipping name: FLAMMABLE LIQUID, N.O.S. (ETHYL ACETATE, NITROCELLULOSE WITH ALCOHOL)

· Air transport ICAO-TI and IATA-DGR:



· ICAO/IATA Class: 3
 · UN/ID Number: 1993
 · Label: 3
 · Packaging group: II
 · Proper shipping name: FLAMMABLE LIQUID, N.O.S. (ETHYL ACETATE, NITROCELLULOSE WITH ALCOHOL)

15 Regulations

· Sara

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

Contact Voco for more informations

141-78-6 ethyl acetate

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

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

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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· **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**

Contact Voco for more informations

· **Canadian Ingredient Disclosure list (limit 0.1%)**

Contact Voco for more informations

· **Canadian Ingredient Disclosure list (limit 1%)**

Contact Voco for more informations

· **Product related hazard informations:**

The product has been classified and marked in accordance with directives on hazardous materials.

· **Hazard symbols:**



Highly flammable

· **Hazard-determining components of labelling:**

sodium fluoride

· **Risk phrases:**

Highly flammable.

Contact with acids liberates toxic gas.

Vapours may cause drowsiness and dizziness.

· **Safety phrases:**

Keep container tightly closed.

Keep away from sources of ignition - No smoking.

Do not breathe fumes/aerosol.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable protective clothing, gloves and eye/face protection.

In case of fire, use sand, carbon dioxide or powdered extinguishing agent. Never use water.

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 MSDS:** Scientific departement

· **Contact:** Tel.: +49 (0)4721-719-0

USA

Safety Data Sheet

acc. to OSHA HCS

Printing date 05/11/2015

Reviewed on 05/11/2015

1 Identification

- **Product identifier**
- **Trade name:** Profluorid L
- **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
- **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. 2 H225 Highly flammable liquid and vapor.



Eye Irrit. 2A H319 Causes serious eye irritation.

STOT SE 3 H336 May cause drowsiness or dizziness.

- **Label elements**

- **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.

- **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.

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3 Composition/information on ingredients

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

- **Dangerous components:**

141-78-6	ethyl acetate	50-100%
9004-70-0	Cellulose nitrate with alcohol	10-25%
105-68-0	isopentyl propionate	10-25%
7681-49-4	sodium fluoride	2.5-5%
	Clove oil	≤ 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.
- **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.
Do not flush with water or aqueous cleansing agents
- **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

- **Precautions for safe handling**
For dental use only.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.

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

Melting point/Melting range:	Undetermined.
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):** 1.01 g/cm³ (8.428 lbs/gal)

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- **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**
- **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.*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *No dangerous decomposition products known.*

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

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

Oral	LD50	5800 mg/kg (mouse)
141-78-6 ethyl acetate		
Oral	LD50	5620 mg/kg (rabbit)
Inhalative	LC50/4 h	1600 mg/l (rat)
7681-49-4 sodium fluoride		
Oral	LD50	52 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:**
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
No irritant effect.
- **on the eye:** *Irritating effect.*
- **Sensitization:** *No sensitizing effects known.*
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed

· **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**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Bioaccumulative potential** *No further relevant information available.*

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- **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.

14 Transport information

- | | |
|---|---|
| · UN-Number | UN1993 |
| · DOT, ADR, IMDG, IATA | |
| · UN proper shipping name | Flammable liquids, n.o.s. (Ethyl acetate, Nitrocellulose with alcohol) |
| · DOT | |
| · ADR | 1993 Flammable liquids, n.o.s. (Ethyl acetate, Nitrocellulose with alcohol) |
| · IMDG, IATA | FLAMMABLE LIQUID, N.O.S. (ETHYL ACETATE, NITROCELLULOSE WITH ALCOHOL) |
| · Transport hazard class(es) | |
| · DOT | |
|  | |
| · Class | 3 Flammable liquids |
| · Label | 3 |
| · ADR, IMDG, IATA | |
|  | |
| · Class | 3 Flammable liquids |
| · Label | 3 |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | II |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Warning: Flammable liquids |
| · Danger code (Kemler): | 33 |
| · EMS Number: | F-E, <u>S-E</u> |

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- | | |
|--|---|
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | UN1993, Flammable liquids, n.o.s. (Ethyl acetate, 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

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients are listed

· **TLV (Threshold Limit Value established by ACGIH)**

7789-75-5 calcium fluoride

A4

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** 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.

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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 MSDS:** Scientific department

· **Contact:** Tel.: +49 (0)4721-719-0

· **Date of preparation / last revision** 05/11/2015 / 6

· **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

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

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

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

USA