

Safety Data Sheet

according to UN GHS (ST/SG/AC.10/11/Rev.10)

Profisil® Fluoride Varnish

Revision: 10.08.2026

Page 1 of 8

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Profisil® Fluoride Varnish

Further trade names

Profisil® Fluoride Varnish Berry, Profisil® Fluoride Varnish Plus Berry, Profisil® Fluoride Varnish Mint, Profisil® Fluoride Varnish Plus Mint, Profisil® Fluoride Varnish Unflavored, Profisil® Fluoride Varnish Plus Unflavored

Safety information for medical devices This product is a finished medical device intended for use in direct contact with the body and intended for end users. It is therefore exempt from the classification and labelling requirements of Regulation (EC) No 1272/2008 (CLP Regulation) pursuant to Article 1(5)(d) of that Regulation. It is also exempt from the requirements regarding safety data sheets under Article 2(6)(c) of Regulation (EC) No 1907/2006 (REACH Regulation). This safety information applies only to the product described in connection with its intended use. In particular, they are intended to describe the product with regard to the hazards it poses and the safety precautions to be taken. The information is based on the current state of our knowledge. It does not constitute a guarantee of product or quality characteristics. In particular, it is intended to provide, on a voluntary basis, sufficient information to ensure the safe use of the product.

1.2. Relevant identified uses of the substance or mixture and uses advised against**Use of the substance/mixture**

Dental Fluoride Varnish.

Medical device for use in dentistry, observe instructions for use.

1.3. Details of the supplier of the safety data sheet

Company name:	Kettenbach GmbH & Co. KG	
Street:	Im Heerfeld 7	
Place:	D-35713 Eschenburg	
Telephone:	+ 49(0) 2774/705-0	Telefax: +49 (0)2774/705-66
E-mail:	info@kettenbach.com	
Internet:	www.kettenbach.com	
Responsible Department:	R&D	

Further Information

The product is intended for professional use.

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****UN GHS (ST/SG/AC.10/11/Rev.10)**

This mixture is not classified as hazardous in accordance with UN-GHS (Rev. 10).

2.2. Label elements**2.3. Other hazards**

None known.

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

Safety Data Sheet

according to UN GHS (ST/SG/AC.10/11/Rev.10)

Profisil® Fluoride Varnish

Revision: 10.08.2026

Page 2 of 8

Chemical characterization

A mixture of polydimethylsiloxanes, 5% sodium fluoride, a film-forming organic polymer and flavouring/sweetener*. *Not included in the "unflavoured" version

(PLUS variant) A mixture of polydimethylsiloxanes, 5% sodium fluoride, hydroxyapatite, calcium salts, phosphate salts, steviol glycosides (stevia)*, xylitol*, film-forming organic polymer, flavouring*. *Not included in the 'unflavoured' version

Hazardous components

CAS No	Chemical name	Quantity
	Classification (UN GHS (ST/SG/AC.10/11/Rev.10))	
7681-49-4	sodium fluoride	>4 - <6 (*) %
	Acute Tox. 3, Skin Irrit. 2, Eye Irrit. 2; H301 H315 H319	

Further Information

(*) The actual concentration is withheld as a trade secret.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

Provide fresh air.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap.
In case of skin reactions, consult a physician.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.
Remove contact lenses, if present and easy to do. Continue rinsing.

After ingestion

Ingestion of large amounts of fluoride due to improper use can lead to nausea, vomiting and diarrhea. Seek medical attention if problems persist.

4.2. Most important symptoms and effects, both acute and delayed

Eye contact: Irritating to eyes.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically. Antidotal dispensation.

Oral administration of a high dose of CaCl₂ or MgSO₄.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

All standard extinguishing agents are suitable.:

Water spray

alcohol resistant foam

Carbon dioxide (CO₂)

Unsuitable extinguishing media

None known.

Safety Data Sheet

according to UN GHS (ST/SG/AC.10/11/Rev.10)

Profisil® Fluoride Varnish

Revision: 10.08.2026

Page 3 of 8

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Hydrogen fluoride, Carbon dioxide (CO₂), Silicon dioxide (SiO₂)

5.3. Advice for firefighters

Thermal decomposition can lead to the escape of irritating gases and vapours.

Additional information

Do not inhale fire fumes. Fight the fire from a safe distance, taking the usual precautions. Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

For non-emergency personnel

Do not breathe mist/vapours/spray.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

For cleaning up

Do not wash off with acidic cleaning agents.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Section 12: Ecological Information (non-mandatory)

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear personal protection equipment (refer to section 8).

Avoid contact with acids.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

When using do not eat, drink, smoke, sniff.

Avoid contact with skin, eyes and clothes.

Thoroughly cleanse your skin after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special requirements.

Keep locked up.

Hints on joint storage

Keep away from food and drink.

Further information on storage conditions

Please pay attention to the information on the package!

SECTION 8: Exposure controls/personal protection

Safety Data Sheet

according to UN GHS (ST/SG/AC.10/11/Rev.10)

Profisil® Fluoride Varnish

Revision: 10.08.2026

Page 4 of 8

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
-	Fluoride (inorganic as F)	-	2.5		TWA (8 h)	WEL
57-55-6	Propane-1,2-diol, particulates	-	10		TWA (8 h)	WEL
57-55-6	Propane-1,2-diol, total vapour and particulates	150	474		TWA (8 h)	WEL

8.2. Exposure controls

Appropriate engineering controls

not applicable

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Protective gloves. (EN ISO 374)

Skin protection

For the protection against direct skin contact, body protective clothing is essential (in addition to the usual working clothes).

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Thermal hazards

None.

Environmental exposure controls

Do not allow to enter into surface water or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Gel	
Colour:	opaque	
Odour:	Various (neutral, minty, berry)	
Odour threshold:	No data available	
Melting point/freezing point:		No data available
Boiling point or initial boiling point and boiling range:		No data available
Flammability:		No data available
Lower explosion limits:		No data available
Upper explosion limits:		No data available
Flash point:		No data available
Auto-ignition temperature:		No data available
Decomposition temperature:		No data available
pH-Value:		Not applicable.
Viscosity / kinematic:		~26000 mm ² /s
Water solubility:		not applicable
Solubility in other solvents		
No data available		
Dissolution rate:		No data available
Partition coefficient n-octanol/water:		No data available
Dispersion stability:		No data available

Safety Data Sheet

according to UN GHS (ST/SG/AC.10/11/Rev.10)

Profisil® Fluoride Varnish

Revision: 10.08.2026

Page 5 of 8

Vapour pressure:	No data available
Vapour pressure:	No data available
Density (at 25 °C):	~0.99 g/cm ³
Relative density:	No data available
Bulk density:	not applicable
Relative vapour density:	not applicable
Particle characteristics:	not applicable

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

Not applicable.

Further Information

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: Stability and reactivity

10.1. Reactivity

None by intended use.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Contact with acids liberates very toxic gas. Hydrogen fluoride (HF)

10.4. Conditions to avoid

Storage outside of the predetermined storage conditions (see packaging)

10.5. Incompatible materials

Strong acid

strong base

Oxidising agent, strong

10.6. Hazardous decomposition products

None by intended use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) 2970 mg/kg; ATE (dermal) > 5000 mg/kg; ATE (inhalation vapour) > 50 mg/l; ATE (inhalation dust/mist) > 12,5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
7681-49-4	sodium fluoride				
	oral	LD50 mg/kg	148,5	Rat	ECHA
	dermal	LD50 mg/kg	>2000		

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Safety Data Sheet

according to UN GHS (ST/SG/AC.10/11/Rev.10)

Profisil® Fluoride Varnish

Revision: 10.08.2026

Page 6 of 8

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

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.

11.2. Information on other hazards

Endocrine disrupting properties

Does not contain any substance with endocrine-disrupting properties in a concentration of 0.1% by weight or more.

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
7681-49-4	sodium fluoride					
	Acute fish toxicity	LC50	113 mg/l	96 h	Gambusia affinis	ECHA
	Acute algae toxicity	ErC50	95,1 mg/l	72 h	Desmodesmus subspicatus	ECHA
	Acute crustacea toxicity	EC50	54,8 mg/l	48 h	Daphnia magna	ECHA

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

None known.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not remove with domestic waste.

Contaminated packaging

Packaging that is uncontaminated and completely empty can be sent for recycling.

Safety Data Sheet

according to UN GHS (ST/SG/AC.10/11/Rev.10)

Profisil® Fluoride Varnish

Revision: 10.08.2026

Page 7 of 8

SECTION 14: Transport information

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

National regulatory information

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,3,5,6,7,8,9,10,11,13,15,16.

Date of preparation / Revised on: 10/08/2026

Version number: 1,03

Replaces version number: 1,02 (19/03/2025)

Abbreviations and acronyms

ATE: Acute toxicity estimate. CAS: Chemical abstracts service. CFR: Code of Federal Regulations. DNEL: Derived No Effect Level EC50: 50% of maximal effective concentration. FDA: Food and Drug Administration. GHS: Globally Harmonised System. IATA: International air transport association. ICAO: Technical instructions for the safe transport of dangerous goods by air. IMDG: International maritime dangerous goods. LC50: Lethal concentration to 50 % of a test population. LD50: Lethal dose to 50% of a test population (median lethal dose). NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PEL: Permissible Exposure Limit. PNEC: Predicted No Effect Concentration. REL: Recommended exposure limit. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. TWA: 8-hour Time Weighted Averages (long-term exposure limit). US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

Key literature references and sources for data

The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.

Further Information

Training instructions: Use only by personnel trained in dentistry.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

Safety Data Sheet

according to UN GHS (ST/SG/AC.10/11/Rev.10)

Profisil® Fluoride Varnish

Revision: 10.08.2026

Page 8 of 8

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