

Safety Data Sheet

according to UK REACH Regulation

Profisil® Fluoride Varnish

Revision date: 24.06.2024

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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

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

GB CLP Regulation

Acute Tox. 4; H302

Full text of hazard statements: see SECTION 16.

Safety Information Sheet for Medical Devices The particulars given in the Safety Information Sheet only apply to the described product in connection with its appropriate utilization. These particulars are based on the latest state of our knowledge and information. They serve the purpose of describing our product under the aspect of hazards caused by such product and pertaining safety actions. They do not constitute any guarantee of product quality and/or quality features. The particulars given in this Safety Information Sheet are not required according to the Article 31 and Annex II of Regulation (EC) No 1907/2006 (REACH Regulation). This product is classified as a medical device. Medical devices are exempt from the labelling provisions. They merely serve the purpose of providing sufficient information on the voluntary basis with a view to ensure the safe utilization of such substance/mixture/product.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

sodium fluoride

Signal word: Warning

Pictograms:



Hazard statements

H302

Harmful if swallowed.

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Precautionary statements

- P280 Wear protective gloves and eye protection/face protection.
P270 Do not eat, drink or smoke when using this product.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501 Dispose of contents/container to nationalen Vorschriften einer Entsorgung.

2.3. Other hazards

No risks worthy of mention.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of Polydimethylsiloxanes, 5% Sodium fluoride, film forming organic polymer and flavor/sweetener*. *not included in the "unflavored" version.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
7681-49-4	sodium fluoride			>4 - <6 %
	231-667-8	009-004-00-7		
	Acute Tox. 3, Skin Irrit. 2, Eye Irrit. 2; H301 H315 H319 EUH032			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
7681-49-4	231-667-8	sodium fluoride	>4 - <6 %
	oral: LD50 = 52 mg/kg		

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.

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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

Water spray
alcohol resistant foam
Carbon dioxide (CO₂)

Unsuitable extinguishing media

None known.

5.2. Special hazards arising from the substance or mixture

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

Hydrogen fluoride, Carbon dioxide (CO₂), Silicon dioxide (SiO₂)

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

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).

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

See SECTION 12: Ecological information

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear personal protection equipment (refer to section 8).

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.

Further information on handling

Keep locked up and out of reach of children.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special requirements.

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Hints on joint storage

Keep away from food and drink.

Further information on storage conditions

Please pay attention to the information on the package!

7.3. Specific end use(s)

not applicable

SECTION 8: Exposure controls/personal protection

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

8.2. Exposure controls

Appropriate engineering controls

not applicable

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Disposable gloves

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	opaque
Odour:	characteristic
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:	No data available
Viscosity / kinematic:	24000-32000 mm ² /s
Water solubility:	not applicable
Solubility in other solvents	
No data available	

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Dissolution rate:	No data available
Partition coefficient n-octanol/water:	No data available
Dispersion stability:	No data available
Vapour pressure:	No data available
Vapour pressure:	No data available
Density (at 25 °C):	0.986 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	
Sustaining combustion:	No data available
Oxidizing 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

No known hazardous reactions.

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

Formaldehyde
hydrofluoric acid

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

Harmful if swallowed.

ATEmix calculated

ATE (oral) 1040 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
7681-49-4	sodium fluoride				
	oral	LD50 52 mg/kg	Rat	RTECS	

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Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects 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

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.

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	925 mg/l	96 h	Gambusia affinis	
	Acute algae toxicity	ErC50	850 mg/l	72 h	Desmodesmus subspicatus	
	Acute crustacea toxicity	EC50	338 mg/l	48 h	Daphnia magna	IUCLID

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.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

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.

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List of Wastes Code - residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing hazardous substances; hazardous waste

List of Wastes Code - used product

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

List of Wastes Code - contaminated packaging

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

Contaminated packaging

Non-contaminated packages may be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

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

Inland waterways transport (ADN)

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

Marine transport (IMDG)

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

Air transport (ICAO-TI/IATA-DGR)

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

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

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Restrictions on use (REACH, annex XVII):

Entry 75

National regulatory information**15.2. Chemical safety assessment**

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information**Changes**

Replaces version number: --

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.

Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Acute Tox. 4; H302	Calculation method

Relevant H and EUH statements (number and full text)

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
EUH032	Contact with acids liberates very toxic gas.

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.

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