Safety Data Sheet

according to 29 CFR 1910.1200(g)

PROFISIL® FREE

1. Identification

Product identifier

PROFISIL® FREE

Further trade names

Profisil Free Unflavored

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. In particular, 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 in accordance with 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 (29 CFR § 1910.1200). 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.

Recommended use of the chemical and restrictions on use

Use of the substance/mixture

Dental Fluoride Varnish.
Medical device for use in dentistry, observe instructions for use.

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.

2. Hazard(s) identification

Classification of the chemical

29 CFR Part 1910.1200

This mixture is not classified as hazardous in accordance with Regulation 29 CFR 1910.1200(d).

Label elements

Hazards not otherwise classified

None known.

3. Composition/information on ingredients

Mixtures

Chemical characterization

A mixture of polydimethylsiloxanes, hydroxyapatite, calcium salts, phosphate salts, and a film-forming organic polymer.

Hazardous components

none (according to 29 CFR 1910.1200(g))

Further Information

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

4. First-aid measures

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

Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

After contact with skin

In general the product is not skin irritative.
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

Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

Most important symptoms and effects, both acute and delayed

Eye contact: Irritating to eyes.

Indication of any immediate medical attention and special treatment needed

First Aid, decontamination, treatment of symptoms.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

All standard extinguishing agents are suitable.:
Water spray
alcohol resistant foam
Carbon dioxide (CO_2)

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

In case of fire may be liberated: Carbon dioxide (CO_2), Silicon dioxide (SiO_2)

Special protective equipment and precautions for fire-fighters

Fire fumes of organic materials are principally classified as toxic upon respiration

Additional information

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

For non-emergency personnel

Do not breathe mist/vapors/spray.

Environmental precautions

Do not allow to enter into surface water or drains.

Methods and material for containment and cleaning up

For containment

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

Reference to other sections

Safe handling: see section 7
Personal protection equipment (PPE): see section 8
Section 12: Ecological Information (non-mandatory)
Disposal: see section 13

7. Handling and storage

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.
Thoroughly cleanse your skin after handling the product.

Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special requirements.

Hints on joint storage

Keep away from food and drink.

Further information on storage conditions

Please pay attention to the information on the package!

8. Exposure controls/personal protection

Control parameters

Additional advice on limit values

To date, no national critical limit values exist.

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

Respiratory protection is not required when used properly and under normal conditions.

Thermal hazards

None.

Environmental exposure controls

Do not allow to enter into surface water or drains.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state:	Gel
Color:	opaque
Odor:	almost odorless
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 mm²/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
Vapor pressure:	No data available
Vapor pressure:	No data available
Density (at 25 °C):	~0.99 g/cm³
Relative density:	No data available
Bulk density:	not applicable
Relative vapour density:	not applicable
Particle characteristics:	not applicable

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.

10. Stability and reactivity

Reactivity

None by intended use.

Chemical stability

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

Possibility of hazardous reactions

None by intended use.

Conditions to avoid

Storage outside of the predetermined storage conditions (see packaging)

Incompatible materials

Strong acid

strong base
Oxidizing agent, strong

Hazardous decomposition products

None by intended use.

11. Toxicological information

Information on toxicological effects

Acute toxicity

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

ATEmix calculated

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

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.

Sensitizing 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.

Specific target organ toxicity (STOT) - single exposure

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

Specific target organ toxicity (STOT) - repeated exposure

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

Carcinogenicity (OSHA):	No ingredient of this mixture is listed.
Carcinogenicity (IARC):	No ingredient of this mixture is listed.
Carcinogenicity (NTP):	No ingredient of this mixture is listed.

Aspiration hazard

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

Information on other hazards

Endocrine disrupting properties

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

12. Ecological information

Persistence and degradability

The product has not been tested.

Bioaccumulative potential

The product has not been tested.

Mobility in soil

The product has not been tested.

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.

Other adverse effects

None known.

Further information

Do not allow to enter into surface water or drains.

13. Disposal considerations

Waste treatment methods

Disposal recommendations

Do not remove with domestic waste. Do not allow to enter drains or watercourses.
Dispose in accordance with official regulations.

Contaminated packaging

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

14. Transport information

U.S. DOT 49 CFR 172.101

Proper shipping name:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

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

Air transport (ICAO-TI/IATA-DGR)

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

Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

Special precautions for user

No dangerous good in sense of this transport regulation.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No dangerous good in sense of this transport regulation.

15. Regulatory information

U.S. Regulations

National Inventory TSCA

Safety Data Sheet according to US OSHA Hazard Communication Standard (29 CFR 1910.1200)

State Regulations

Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, State of California)

This product can not expose you to chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

16. Other information

Hazardous Materials Identification System (HMIS)

Health:	1
Flammability:	1
Physical Hazard:	0
Personal Protection:	B

NFPA Hazard Ratings



Health:	1
Flammability:	1
Reactivity:	1
Unique Hazard:	None

Changes

Revision date:	08/10/2026
Revision No:	1,00

Date of preparation / Revised on: 10/08/2026
Version number: 1,00
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.

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.

Other data

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.)