

**Safety data sheet according to Regulation (EC)
No. 1907/2006 (REACH), Article 31**

Version number: 1.3 / Creation date: 01.09.2021

Combiflex Putty

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Combiflex Putty / Article number #14600247
UFI-Code: 9ACC-2264-EC1Q-XK88

1.2. Relevant identified uses of the substance or mixture

Use of the substance/mixture Silicone material for dental purposes.

1.3. Details of the supplier of the safety data sheet

Company name: Baumann Dental GmbH
Street/P.O. Box: Im Hölderle 5
Post code, Place: D-75196 Remchingen
Internet: www.baumann-dental.de
@-mail: info@baumann-dental.de
Telephone: +49 (0) 7232 - 73218 - 0
Telefax: +49 (0) 7232 - 73218 - 99
Department responsible for information:
Telephone: +49 (0) 7232 - 73218 - 0
E-mail: info@baumann-dental.de

1.4. Emergency telephone number

Germany: +49(0)551-19240 (Poison Information Centre North, 24h in German and English)
Austria: +43(0)1-4064343 (Poison Information Centre, 24h)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture Regulation (EC) No. 1272/2008

The mixture is not classified as dangerous within the meaning of Regulation (EC) No 1272/2008.

2.2. Label elements Regulation (EC) No. 1272/2008

Special labelling of specific mixtures:
EUH210 Safety data sheet available upon request.

2.3. Other hazards

There is no information available.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

Classification according to Regulation (EC) / 1272/2008 (CLP)

CAS No.	Designation	REACH No.	Percentage
14464-46-1	Cristobalite flour		30 - < 35%
	EC No. 238-455-4 STOT RE 1; H372		
8042-47-5	Paraffin oil		1 - < 5%
	EC No. 232-455-8 Asp. Tox. 1; H304	01-2119487078-27	

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SECTION 4: First aid measures

4.1. Description of first aid measures

If inhaled: Provide for fresh air. Medical treatment necessary.

Following skin contact: Remove product mechanically with a cloth or paper wipe. Wash off with plenty of soap and water. In case of visible skin change or discomfort, seek medical advice (show label or safety data sheet if possible).

Following eye contact: Immediately rinse carefully and thoroughly with eye wash or water.
Consult an ophthalmologist.

If swallowed: Rinse mouth immediately and drink copious amounts of water. Allow to drink copious amounts of water in small sips (dilution effect). Consult doctor immediately. Do not induce vomiting. In case of spontaneous vomiting, ensure that vomit can flow off unhindered due to the risk of suffocation.

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

There is no information available.

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

Symptomatic treatment.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media:

Adapt extinguishing measures to the surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable. Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

In case of fire: wear self-contained breathing apparatus.

Additional notes:

Use a water spray to protect persons and cool containers in the danger area.

Suppress gases/vapours/mist with water spray. Collect contaminated extinguishing water separately.

Do not allow to enter the sewage system or waters.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Do not inhale gas/smoke/vapour/aerosol. Avoid contact with skin, eyes and clothing. Use personal protective equipment.

6.2. Environmental precautions

Do not allow to enter the sewage system or waters.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders). Treat the collected material according to the section on disposal.

6.4. Reference to other sections

For safe handling: see Section 7

Personal protective equipment: see Section 8

Disposal: see Section 13

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Instructions for safe handling: in case of open handling, devices with local ventilation must be used.

Do not inhale gas/smoke/vapour/aerosol.

Notes on fire and explosion protection: no special fire protection measures required.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers tightly closed. Store locked up. Store in a place only accessible to authorised persons. Ensure adequate ventilation and selective extraction at critical points.

Information on common storage:

No special preventive measures required.

Further information on storage conditions:

Only store in original containers in a cool and dry place, away from foodstuffs.

Ensure good room ventilation.

7.3. Specific end use(s)

Laboratory putty for dental technology.

For use by trained specialist personnel.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls:

In case of open handling, devices with local ventilation must be used.

Do not inhale gas/smoke/vapour/aerosol.

Protection and hygiene measures:

Take off contaminated, soaked clothing immediately. Prepare and observe skin protection plan! Wash hands and face thoroughly prior to breaks and at the end of work, if necessary, take a shower. Do not eat and drink during work.

Eye and face protection

Wear eye/face protection.

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Hand protection:

When handling chemical substances, only chemical protective gloves with the CE mark including a four-digit test number may be worn. Chemical protective gloves must be selected specifically for the workplace depending on the concentration and quantity of hazardous substances. It is recommended to check the chemical resistance of the above mentioned protective gloves for specific applications with the glove manufacturer. Protective gloves made of the following material are suitable: NBR (nitrile butadiene rubber)

Body protection:

Wear suitable protective clothing at work.

Breathing protection:

Wear respiratory protection in case of insufficient ventilation.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aggregate state:	paste	
Colour:	grey	
Odour:	characteristic	
	Test standard	
pH value:	not determined	
Changes of state		
Melting point:	not determined	
Initial boiling point and boiling range:	not determined	
Flash point:	>100°C	DIN 51755
Flammability		
Solid:	not applicable	
Gas:	not applicable	
Lower explosion threshold:	not determined	
Upper explosion threshold:	not determined	
Ignition temperature:	>200°C	DIN 51794
Auto-ignition temperature		
Solid:	not applicable	
Gas:	not applicable	
Decomposition temperature:	>250°C	
Oxidising properties		
Non-oxidising.		
Vapour pressure (at 20°C):	<1 hPa	
Density (at 20°C):	1.67 g/cm ³	DIN 51757
Water solubility	virtually insoluble	
Solubility in other solvents:	not determined	
Distribution coefficient:	not determined	
Dyn. viscosity (at 23°C):	25,000,000 mPa·s BROOKFIELD	
Vapour density:	not determined	
Evaporation rate:	not determined	

9.2. Other information

Solids content:	not determined
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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No hazardous reactions occur if handled and stored as directed.

10.2. Chemical stability

The product is stable when stored at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

Temperatures > 150°C.

10.5. Incompatible materials

There is no information available.

10.6. Hazardous decomposition products

In the presence of air, small amounts of formaldehyde can be formed by oxidative degradation at temperatures of approx. 150°C and above.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

Based on the available data, the classification criteria are not met. No toxicological data are available for the product.

An LD50 (oral, rat) of >5000 mg/kg was found for products of similar composition

CAS No.	Designation			
	Exposition route	Dose	Species	Source
8042-47-5	Paraffin oil			
	oral	LD50 >5000 mg/kg	rats	OECD
	dermal	LD50 >2000 mg/kg	rabbits	OECD

Irritant and caustic effect:

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

Sensitising effects:

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

Carcinogenic, mutagenic and teratogenic effects:

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

Specific target organ toxicity at single exposure:

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

Specific target organ toxicity at repeated exposure

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Specific target organ toxicity at repeated exposure

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

Due to the physical form (paste) a classification with H372 is not indicated.

Inhalation is not possible.

EU Regulation 1278/2008 Annex 1, Point 1.1.1.5: "In the classification of health hazards (Part 3), the route of exposure, mechanical data and metabolic studies are of concern for determining the relevance of an effect in humans. If such information makes the relevance for humans doubtful, a weaker classification may be justified if the reliability and quality of the data are confirmed. If there is scientific evidence that the mechanism of action or mode of action is not relevant to humans, the substance or mixture should not be classified.

Aspiration hazard:

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

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

The product is not ecotoxic.

CAS No.	Designation			
	Aquatic toxicity	Dose	[h] [d]	Species
8042-47-5	Paraffin oil			
	Acute fish toxicity	LC50 >1000 mg/l	96 h	Leuciscus idus (ide)
				OECD

12.2. Persistence and degradability

The product was not tested.

12.3. Bioaccumulative potential

The product was not tested.

12.4. Mobility in soil

The product was not tested.

12.5. Results of PBT and vPvB assessment

Not classified as PBT or vPvB

12.6. Other adverse effects

There is no information available.

Further information

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Recommendation:

Do not allow to enter the sewage system or waters. Disposal in accordance with official regulations.

Disposal of uncleaned packaging and recommended cleaning agents:

This product and its container must be disposed of as hazardous waste.

Contaminated packaging is to be treated same as the substance.

SECTION 14: TRANSPORT INFORMATION

Surface Transport (ADR/RID)

14.1. UN number:

Not dangerous goods within the meaning of these transport regulations.

14.2. Proper UN shipping name:

Not dangerous goods within the meaning of these transport regulations.

14.3. Transport hazard classes:

Not dangerous goods within the meaning of these transport regulations.

14.4. Packaging group:

Not dangerous goods within the meaning of these transport regulations.

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Inland waterway transport (ADN)

14.1. UN number:	Not dangerous goods within the meaning of these transport regulations.
14.2. Proper UN shipping name:	Not dangerous goods within the meaning of these transport regulations.
14.3. Transport hazard classes:	Not dangerous goods within the meaning of these transport regulations.
14.4. Packaging group:	Not dangerous goods within the meaning of these transport regulations.

Transport by sea (IMDG)

14.1. UN number:	Not dangerous goods within the meaning of these transport regulations.
14.2. Proper UN shipping name:	Not dangerous goods within the meaning of these transport regulations.
14.3. Transport hazard classes:	Not dangerous goods within the meaning of these transport regulations.
14.4. Packaging group:	Not dangerous goods within the meaning of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	Not dangerous goods within the meaning of these transport regulations.
14.2. Proper UN shipping name:	Not dangerous goods within the meaning of these transport regulations.
14.3. Transport hazard classes:	Not dangerous goods within the meaning of these transport regulations.
14.4. Packaging group:	Not dangerous goods within the meaning of these transport regulations.

14.6. Special precautions for user

Not dangerous goods within the meaning of these transport regulations.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Not dangerous goods within the meaning of these transport regulations.

SECTION 15: REGULATORY INFORMATION

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

EU regulations:

Additional notes:

To be observed: 850/2004/EC, 79/117/EEC, 689/2008/EC

National regulations:

Employment restrictions: Observe employment restrictions for adolescents (§ 22 ArbSchG [German Young Persons Employment Act]).
Observe employment restrictions for expectant and breastfeeding mothers (§§ 4 and 5 MuSchArbV [German Maternity Protection Act]).

Water hazard class:

1 - slightly hazardous to water

Status:

Mixing rule according to VwVwS Annex 4, No. 3 [German Administrative Regulation Regarding Water Pollutants]

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture have not been conducted.

SECTION 16: OTHER INFORMATION

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
LC50:	Lethal concentration, 50%
LD50:	Lethal dose, 50%

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Wording of the H and EUH phrases (number and full text)

H304 May be fatal if swallowed and enters airways.

H372 Damages the organs (lungs) by prolonged or repeated exposure through inhalation.

EUH210 Safety data sheet available upon request.

Further information:

To the best of our knowledge, the information in this safety data sheet corresponds to our information at the time of printing. This information is intended to provide you with information for the safe handling of the product named in this safety data sheet during storage, processing, transport and disposal. The information is not transferable to other products. Insofar as the product is combined, mixed or processed with other materials or undergoes processing, the information in this safety data sheet cannot be transferred to the new material produced in this manner, unless expressly stated otherwise.