

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

### exaplast putty

Revision date: 25.10.2022

Product code: 10931

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## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

exaplast putty

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### Use of the substance/mixture

Impression material for use in dental technology.

### 1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH	
Street:	Carl-Zeiss-Straße 4	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.com	
Internet:	www.detax.com	
Responsible Department:	This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)	

### 1.4. Emergency telephone number:

+1-800-424-9300 (CHEMTREC worldwide)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Regulation (EC) No. 1907/2006

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

### 2.2. Label elements

#### Regulation (EC) No. 1907/2006

#### Special labelling of certain mixtures

EUH208 Contains carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one. May produce an allergic reaction.

#### Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

### 2.3. Other hazards

No information available.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Chemical characterization

Contains polydimethylsiloxane with functional groups. + fillers and pigment

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#### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No. 1907/2006)			
14464-46-1	cristobalite flour			5 - < 20 %
	238-455-4			
	STOT RE 1; H372			
8042-47-5	paraffin oil			5 - < 20 %
	232-455-8		01-2119487078-27	
	Asp. Tox. 1; H304			
99-49-0	carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one			0.1 - < 5 %
	202-759-5	606-148-00-8		
	Skin Sens. 1; H317			

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		
8042-47-5	232-455-8	paraffin oil	5 - < 20 %
	inhalation: LC50 = >5 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg		

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### After inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

##### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention. Remove product mechanically with cloth or paper. Wash with plenty of water and soap. In case of visible changes on the skin or complaints, seek medical advice (if possible have label or safety data sheet with you).

##### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

##### After ingestion

Let water be drunken in little sips (dilution effect).  
Do not induce vomiting. If you feel unwell, seek medical advice.

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

No information available.

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

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

##### Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

#### 5.2. Special hazards arising from the substance or mixture

Non-flammable.

#### 5.3. Advice for firefighters

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

#### Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

### 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 cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

#### 6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

##### Advice on safe handling

No special measures are necessary.

##### Advice on protection against fire and explosion

No special fire protection measures are necessary.

##### Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

#### 7.2. Conditions for safe storage, including any incompatibilities

##### Requirements for storage rooms and vessels

Keep container tightly closed.

##### Hints on joint storage

No special measures are necessary.

##### Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

#### 7.3. Specific end use(s)

Component B of a silicone based dental impression material.

For use by trained specialist staff.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
9005-25-8	Starch, respirable	-	4		TWA (8 h)	WEL
14807-96-6	Talc respirable dust	-	1		TWA (8 h)	WEL

#### 8.2. Exposure controls

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#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Wear eye/face protection.

##### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: NBR (Nitrile rubber)

##### Skin protection

Use of protective clothing.

##### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:	Paste
Colour:	yellow
Odour:	like peppermint

#### Test method

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	>200 °C
Flammability	
Solid/liquid:	not determined
Gas:	not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	>170 °C DIN 51755
Auto-ignition temperature:	365 °C DIN 51794
Decomposition temperature:	>250 °C
pH-Value:	not determined
Water solubility:	practically insoluble
Solubility in other solvents	
not determined	
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	<1 hPa
(at 20 °C)	
Density (at 20 °C):	1,45 g/cm <sup>3</sup> DIN 51757
Relative vapour density:	not determined

### 9.2. Other information

#### Information with regard to physical hazard classes

##### Explosive properties

The product is not: Explosive.

##### Oxidizing properties

The product is not: oxidising.

#### Other safety characteristics

Evaporation rate: not determined

Solid content: not determined

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Viscosity / dynamic:  
(at 23 °C)

9000000 mPa·s BROOKFIELD

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

### 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

### 10.3. Possibility of hazardous reactions

No known hazardous reactions.

### 10.4. Conditions to avoid

Temperatures > 150°C/ 302 °F.

### 10.5. Incompatible materials

No information available.

### 10.6. Hazardous decomposition products

At a temperature of approx. 150°C/ 302°F a small amount of formaldehyde can be released by oxidative degradation.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No. 1907/2006

#### Acute toxicity

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

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
8042-47-5	paraffin oil				
	oral	LD50 >5000 mg/kg	Rat	OECD	
	dermal	LD50 >2000 mg/kg	Rabbit	OECD	
	inhalation (4 h) vapour	LC50 >5 mg/l	Rat	OECD	

#### Irritation and corrosivity

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

#### Sensitising effects

Contains carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one. May produce an allergic reaction.

#### 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

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

Due to physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible.

EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

#### Aspiration hazard

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

#### Further information

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

### SECTION 12: Ecological information

#### 12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
8042-47-5	paraffin oil					
	Acute fish toxicity	LC50 mg/l	>1000	96 h	Leuciscus idus (golden orfe)	OECD
	Acute algae toxicity	ErC50 mg/l	>100	72 h	Pseudokirchneriella subcapitata	OECD
	Acute crustacea toxicity	EC50 mg/l	>100	48 h	Daphnia magna (Big water flea)	

#### 12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
8042-47-5	paraffin oil				
	OECD 301F/ ISO 9408/ EEC 92/69/V, C.4-D	31%	28		
	Not readily biodegradable (according to OECD criteria)				

#### 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.

Not identified as PBT/ vPvB substances

#### 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

No information available.

#### Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

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## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

#### Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

## 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

Restrictions on use (REACH, annex XVII):

Entry 75

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

#### National regulatory information

Water hazard class (D): 3 - highly hazardous to water  
 Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

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#### 15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

#### **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 Harmonized 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%  
CLP: Classification, labelling and Packaging  
REACH: Registration, Evaluation and Authorization of Chemicals  
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals  
UN: United Nations  
DNEL: Derived No Effect Level  
DMEL: Derived Minimal Effect Level  
PNEC: Predicted No Effect Concentration  
ATE: Acute toxicity estimate  
LL50: Lethal loading, 50%  
EL50: Effect loading, 50%  
EC50: Effective Concentration 50%  
ErC50: Effective Concentration 50%, growth rate  
NOEC: No Observed Effect Concentration  
BCF: Bio-concentration factor  
PBT: persistent, bioaccumulative, toxic  
vPvB: very persistent, very bioaccumulative  
RID: Regulations concerning the international carriage of dangerous goods by rail  
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)  
EmS: Emergency Schedules  
MFAG: Medical First Aid Guide  
ICAO: International Civil Aviation Organization  
MARPOL: International Convention for the Prevention of Marine Pollution from Ships  
IBC: Intermediate Bulk Container  
SVHC: Substance of Very High Concern  
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

##### **Relevant H and EUH statements (number and full text)**

H304	May be fatal if swallowed and enters airways.
H317	May cause an allergic skin reaction.
H372	Causes damage to organs (lung) through prolonged or repeated exposure if inhaled.
EUH208	Contains carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one. May produce an allergic reaction.

##### **Further Information**

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible



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for adhering to existing laws and regulations.

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