

according to Regulation (EC) No 1907/2006

### exagel cat

Revision date: 10.08.2017

Product code: 10178

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

### 1.1. Product identifier

exagel cat

### 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 & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	

+49 7243/510-0

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:

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Regulation (EC) No. 1272/2008

Hazard categories:

Acute toxicity: Acute Tox. 4

Acute toxicity: Acute Tox. 4

Serious eye damage/eye irritation: Eye Irrit. 2

Germ cell mutagenicity: Muta. 2

Reproductive toxicity: Repr. 1A

Specific target organ toxicity - repeated exposure: STOT RE 1

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Harmful if inhaled.

Harmful if swallowed.

Causes serious eye irritation.

Suspected of causing genetic defects.

May damage fertility.

Causes damage to organs through prolonged or repeated exposure.

Harmful to aquatic life with long lasting effects.

### 2.2. Label elements

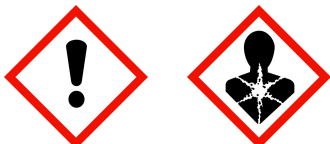
#### Regulation (EC) No. 1272/2008

#### Hazard components for labelling

alkylstannonic siloxanes

Signal word: Danger

#### Pictograms:



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#### Hazard statements

H302+H332	Harmful if swallowed or if inhaled.
H319	Causes serious eye irritation.
H341	Suspected of causing genetic defects.
H360F	May damage fertility.
H372	Causes damage to organs (Thymus) through prolonged or repeated exposure if swallowed.
H412	Harmful to aquatic life with long lasting effects.

#### Precautionary statements

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P310	Immediately call a POISON CENTER/doctor.

#### Special labelling of certain mixtures

EUH208	Contains menthone. May produce an allergic reaction.
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#### 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

Silicon-tin-compound with auxilliary matters.

##### Hazardous components

CAS No	Chemical name	Quantity
	EC No	Index No
	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
93925-42-9	alkylstannonic siloxanes	65 - < 70 %
	300-344-4	01-2119560586-30
	Flam. Liq. 3, Muta. 2, Repr. 1, Acute Tox. 4, Acute Tox. 4, Eye Dam. 1, STOT RE 1, Aquatic Chronic 3; H226 H341 H360F H332 H302 H318 H372 H412	
89-80-5	menthone	< 1 %
	201-941-1	
	Skin Irrit. 2, Skin Sens. 1B; H315 H317	

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

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

##### After inhalation

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

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**After contact with skin**

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention.

**After contact with eyes**

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

**After ingestion**

Rinse mouth immediately and drink plenty of water. Let water be drunken in little sips (dilution effect). Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

**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**

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

**Additional information**

Suppress gases/vapours/mists with water spray jet. 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**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. 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**

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

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

**Advice on protection against fire and explosion**

No special fire protection measures are necessary.

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**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations.

**Advice on storage compatibility**

Do not store with strong oxidising materials.

**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 A of a silicone based dental impression material.

For use by trained specialist staff.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****8.2. Exposure controls****Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

**Protective and hygiene measures**

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.

**Eye/face protection**

Suitable eye protection: goggles.

**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), Butyl caoutchouc (butyl rubber), FKM (fluoro rubber), CR (polychloroprene, chloroprene rubber)

**Skin protection**

Wear suitable 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:	blue
Odour:	like peppermint

**Test method**

pH-Value:	not determined
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**Changes in the physical state**

Melting point:	not determined
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Initial boiling point and boiling range:	>200 °C DIN 51356
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Flash point:	>100 °C	DIN 51755
<b>Flammability</b>		
Solid:	not applicable	
Gas:	not applicable	
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Ignition temperature:	>300 °C	DIN 51794
<b>Auto-ignition temperature</b>		
Solid:	not applicable	
Gas:	not applicable	
Decomposition temperature:	>250 °C	
<b>Oxidizing properties</b>		
Not oxidizing.		
Vapour pressure: (at 20 °C)	<1 hPa	
Density (at 20 °C):	1,0 g/cm <sup>3</sup>	DIN 51757
Water solubility:	insoluble	
<b>Solubility in other solvents</b>		
not determined		
Partition coefficient:	not determined	
Viscosity / dynamic: (at 23 °C)	>80000 mPa·s	BROOKFIELD
Vapour density:	not determined	
Evaporation rate:	not determined	
<b>9.2. Other information</b>		
Solid content:	not determined	

## 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

Reacts with : strong oxidising agents.

### 10.4. Conditions to avoid

Higher temperatures advance the formation of flammable vapours, therefore don't expose the product to increased temperatures.

### 10.5. Incompatible materials

No information available.

### 10.6. Hazardous decomposition products

No known hazardous decomposition products.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

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#### Acute toxicity

Harmful if swallowed or if inhaled.

For the product itself no toxicological data are available. In products with a comparable composition a LD50 (orally, species rat) of >2000 mg/kg has been found.

#### ATEmix calculated

ATE (oral) 741,4 mg/kg; ATE (inhalative vapour) 16,31 mg/l; ATE (inhalative aerosol) 2,224 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
93925-42-9	alkylstannonic siloxanes				
	oral	ATE 500 mg/kg			
	inhalative vapour	ATE 11 mg/l			
	inhalative aerosol	ATE 1,5 mg/l			

#### Irritation and corrosivity

Causes serious eye irritation.

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

Based on a Bovine Corneal Permeability Study conducted in accordance with OECD Guideline No. 437 (July 2013), H318 is not shown.

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."

#### Sensitising effects

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

#### Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of causing genetic defects. (alkylstannonic siloxanes)

May damage fertility. (alkylstannonic siloxanes)

Carcinogenicity: 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

Causes damage to organs (Thymus) through prolonged or repeated exposure if swallowed. (alkylstannonic siloxanes)

#### Aspiration hazard

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

#### Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP]. Special hazards arising from the substance or mixture!

## SECTION 12: Ecological information

### 12.1. Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### 12.2. Persistence and degradability

The product has not been tested.

### 12.3. Bioaccumulative potential

The product has not been tested.

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**12.4. Mobility in soil**

The product has not been tested.

**12.5. Results of PBT and vPvB assessment**

The product has not been tested.

**12.6. 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.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Advice on disposal**

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**

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

**SECTION 14: Transport information****Land transport (ADR/RID)****14.1. UN 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.

**Inland waterways transport (ADN)****14.1. UN 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.

**Marine transport (IMDG)****14.1. UN 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:**

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.

**14.6. Special precautions for user**

No dangerous good in sense of this transport regulation.

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

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**

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#### National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water contaminating class (D): 3 - highly water contaminating

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

#### 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%

#### Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Acute Tox. 4; H332	Calculation method
Acute Tox. 4; H302	Calculation method
Eye Irrit. 2; H319	
Muta. 2; H341	Calculation method
Repr. 1A; H360F	Calculation method
STOT RE 1; H372	Calculation method
Aquatic Chronic 3; H412	Calculation method

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

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H302+H332 Harmful if swallowed or if inhaled.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H341 Suspected of causing genetic defects.

H360F May damage fertility.

H372 Causes damage to organs (Thymus) through prolonged or repeated exposure if swallowed.

H412 Harmful to aquatic life with long lasting effects.

EUH208 Contains menthone. May produce an allergic reaction.

#### Further Information

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

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

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**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 & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	

+49 7243/510-0

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:**

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Special labelling of certain mixtures**

EUH208 Contains 2-methyl-5-(1-methylvinyl)cyclohex-2-en-1-one. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

**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 according to Regulation (EC) No. 1272/2008 [CLP]			
14464-46-1	crystalite flour			10 - < 20 %
	238-455-4			
	STOT RE 1; H372			
8042-47-5	paraffin oil			5 - < 10 %
	232-455-8		01-2119487078-27	
	Asp. Tox. 1; H304			

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

### 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

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

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

##### After ingestion

Rinse mouth thoroughly with water. Let water be drunk 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. Vapours can form explosive mixtures with air.

#### 5.3. Advice for firefighters

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

#### Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. 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

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and

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clothes. 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**

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

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

**Advice on protection against fire and explosion**

No special fire protection measures are necessary.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

**Advice on storage compatibility**

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****8.2. Exposure controls****Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

**Protective and hygiene measures**

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.

**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)

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#### Skin protection

Wear suitable 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

pH-Value: not determined

#### Changes in the physical 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 limits: not determined  
 Upper explosion limits: not determined

Ignition temperature: >200 °C DIN 51794

#### Auto-ignition temperature

Solid: not applicable  
 Gas: not applicable

Decomposition temperature: >250 °C

#### Oxidizing properties

Not oxidizing.

Vapour pressure: <1 hPa  
 (at 20 °C)

Density (at 20 °C): 1,45 g/cm<sup>3</sup> DIN 51757

Water solubility: practically insoluble

#### Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic: 9000000 mPa·s BROOKFIELD  
 (at 23 °C)

Vapour density: not determined

Evaporation rate: not determined

### 9.2. Other information

Solid content: not determined

## SECTION 10: Stability and reactivity

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#### 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 toxicological effects

##### 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
8042-47-5	paraffin oil			
	oral	LD50 >5000 mg/kg	Rat	OECD
	dermal	LD50 >2000 mg/kg	Rabbit	OECD

##### Irritation and corrosivity

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

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.

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.

### SECTION 12: Ecological information

according to Regulation (EC) No 1907/2006

### exaplast putty

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#### 12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name				
	Aquatic toxicity	Dose	[h]   [d]	Species	Source
8042-47-5	paraffin oil				
	Acute fish toxicity	LC50 >1000 mg/l	96 h	Leuciscus idus (golden orfe)	OECD

#### 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

Not identified as PBT/ vPvB substances

#### 12.6. Other adverse effects

No information available.

#### Further information

Avoid release to the environment.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### Advice on disposal

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

##### Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

### SECTION 14: Transport information

#### Land transport (ADR/RID)

##### 14.1. UN 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.

#### Inland waterways transport (ADN)

##### 14.1. UN 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.

#### Marine transport (IMDG)

##### 14.1. UN 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)

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- 14.1. UN 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.

**14.6. Special precautions for user**

No dangerous good in sense of this transport regulation.

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

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

**National regulatory information**

- Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.  
 Water contaminating class (D): 1 - slightly water contaminating  
 Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

### 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%

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

- H304 May be fatal if swallowed and enters airways.  
 H372 Causes damage to organs (lung) through prolonged or repeated exposure if inhaled.  
 EUH208 Contains 2-methyl-5-(1-methylvinyl)cyclohex-2-en-1-one. May produce an allergic reaction.  
 EUH210 Safety data sheet available on request.

**Further Information**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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



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

#### 1.1. Product identifier

exasoft wash

#### 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 & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	

+49 7243/510-0

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:

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

#### 2.2. Label elements

##### Regulation (EC) No. 1272/2008

##### Special labelling of certain mixtures

EUH210 Safety data sheet available on request.

##### 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 according to Regulation (EC) No. 1272/2008 [CLP]			
14808-60-7	quartz			10 - < 15 %
	238-878-4			
	STOT RE 1; H372			
14464-46-1	cristobalite flour			5 - < 10 %
	238-455-4			
	STOT RE 1; H372			
556-67-2	octamethylcyclotetrasiloxane			< 0,5 %
	209-136-7	014-018-00-1	01-2119529238-36	
	Flam. Liq. 3, Repr. 2, Aquatic Chronic 4; H226 H361f H413			

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

**SECTION 4: First aid measures**
**4.1. Description of first aid measures**
**After inhalation**

Provide fresh air. Medical treatment necessary.

**After contact with skin**

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**

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

**After ingestion**

Rinse mouth thoroughly with water. 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. Vapours can form explosive mixtures with air.

**5.3. Advice for firefighters**

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

**Additional information**

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet.

**SECTION 6: Accidental release measures**

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#### **6.1. Personal precautions, protective equipment and emergency procedures**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

#### **6.2. Environmental precautions**

No special environmental measures are necessary. Clean contaminated objects and areas thoroughly observing environmental regulations.

#### **6.3. Methods and material for containment and cleaning up**

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

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

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

No special fire protection measures are necessary.

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

##### **Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

##### **Advice on storage compatibility**

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**

#### **8.2. Exposure controls**

##### **Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

##### **Protective and hygiene measures**

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.

##### **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

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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

Wear suitable 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:	pink
Odour:	odourless

#### Test method

pH-Value:	not determined
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#### Changes in the physical state

Melting point:	not determined
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Initial boiling point and boiling range:	not determined
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Flash point:	>100 °C	DIN 51755
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#### Flammability

Solid:	not applicable
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Gas:	not applicable
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Lower explosion limits:	not determined
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Upper explosion limits:	not determined
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Ignition temperature:	>200 °C	DIN 51794
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#### Auto-ignition temperature

Solid:	not applicable
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Gas:	not applicable
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Decomposition temperature:	>250 °C
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#### Oxidizing properties

Not oxidizing.

Vapour pressure: (at 20 °C)	<1 hPa
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Density (at 20 °C):	1,19 g/cm <sup>3</sup>	DIN 51757
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Water solubility:	practically insoluble
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#### Solubility in other solvents

not determined

Partition coefficient:	not determined
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Viscosity / dynamic: (at 23 °C)	18000 mPa·s	BROOKFIELD
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Vapour density:	not determined
-----------------	----------------

Evaporation rate:	not determined
-------------------	----------------

### 9.2. Other information

Solid content:	not determined
----------------	----------------

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## 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 toxicological effects

#### 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
556-67-2	octamethylcyclotetrasiloxane				
	oral	LD50 mg/kg	4800	Rat	OECD 401
	dermal	LD50 mg/kg	>2400	Rabbit	OECD 402
	inhalation (4 h) vapour	LC50	36 mg/l	Rat	GESTIS OECD 403

#### Irritation and corrosivity

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

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. Due to physical form (paste) classification with H373 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.

## SECTION 12: Ecological information

### 12.1. Toxicity

The product is not: Ecotoxic.

### 12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name	Method	Value	d	Source
		Evaluation			
556-67-2	octamethylcyclotetrasiloxane		3,7%	29	
	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

Octamethylcyclotetrasiloxane (D4) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for PBT and vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D4 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D4 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D4 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

### 12.6. Other adverse effects

No information available.

#### Further information

Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Advice on disposal

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

#### Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

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### SECTION 14: Transport information

#### Land transport (ADR/RID)

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

#### Inland waterways transport (ADN)

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

#### Marine transport (IMDG)

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

#### Air transport (ICAO-TI/IATA-DGR)

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

#### **14.6. Special precautions for user**

No dangerous good in sense of this transport regulation.

#### **14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

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

##### Additional information

The mixture contains substances of very high concern (SVHC candidates):  
Octamethylcyclotetrasiloxane (D4), CAS no. 556-67-2

##### National regulatory information

Employment restrictions:	Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.
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Water contaminating class (D):	-- not water contaminating
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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)

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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%

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

H226	Flammable liquid and vapour.
H361f	Suspected of damaging fertility.
H413	May cause long lasting harmful effects to aquatic life.
EUH210	Safety data sheet available on request.

**Further Information**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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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.)*