

## Safety Data Sheet

according to UK REACH Regulation

### addition protect (base + catalyst)

Revision date: 04.04.2022

Product code: 10381

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

### 1.1. Product identifier

addition protect (base + catalyst)

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

#### Use of the substance/mixture

Impression material for use in audiology.

### 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

#### GB CLP Regulation

Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

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

### 2.2. Label elements

#### GB CLP Regulation

##### Hazard statements

H412 Harmful to aquatic life with long lasting effects.

##### Precautionary statements

P273	Avoid release to the environment.
P501	Dispose of contents/container to according to local and applicable legislation of dispose of waste.

##### 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

The mixture contains the following substances fulfilling the PBT criteria according to UK REACH:

Dodecamethylcyclohexasiloxane.

The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:

Decamethylcyclopentasiloxane.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Chemical characterization

Contains polydimethylsiloxane with functional groups. + fillers and pigment catalyst: additionally platinum complex compound.

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#### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
14464-46-1	cristobalite flour			20 - < 40 %
	238-455-4			
	STOT RE 1; H372			
8042-47-5	paraffin oil			0.1 - < 5 %
	232-455-8		01-2119487078-27	
	Asp. Tox. 1; H304			
540-97-6	Dodecamethylcyclohexasiloxane			0.1 - < 5 %
	208-762-8		01-2119517435-42	
541-02-6	Decamethylcyclopentasiloxane			0.1 - < 5 %
	208-764-9		01-2119511367-43	
556-67-2	Octamethylcyclotetrasiloxane			< 0.1 %
	209-136-7	014-018-00-1	01-2119529238-36	
	Flam. Liq. 3, Repr. 2, Aquatic Chronic 1; H226 H361f H410			

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	0.1 - < 5 %
		inhalation: LC50 = >5 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
540-97-6	208-762-8	Dodecamethylcyclohexasiloxane	0.1 - < 5 %
		dermal: LD50 = 2000 mg/kg; oral: LD50 = 2000 mg/kg	
541-02-6	208-764-9	Decamethylcyclopentasiloxane	0.1 - < 5 %
		inhalation: LC50 = 8,67 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >24100 mg/kg	
556-67-2	209-136-7	Octamethylcyclotetrasiloxane	< 0.1 %
		inhalation: LC50 = 36 mg/l (vapours); dermal: LD50 = >2400 mg/kg; oral: LD50 = 4800 mg/kg M chron.; H410: M=10	

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### After inhalation

Provide fresh air.

##### After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

##### After contact with eyes

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

##### After ingestion

Rinse mouth immediately and drink 1 glass of of water. Rinse mouth immediately and drink plenty of water. Let water be drunken in little sips (dilution effect).

Do not induce vomiting. If you feel unwell, seek medical advice.

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#### **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**

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.

##### **Other information**

Absorb with liquid-binding material (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**

No special measures are necessary.

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

No special fire protection measures are necessary.

##### **Advice on general occupational hygiene**

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff. Take off contaminated clothing. Wash hands before breaks and after work. 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**

Do not store with acids, lyes, alcohols, metallic powders and metallic oxides (release of hydrogen is favoured).

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#### 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)

Ear impression material.

For use by trained specialist staff.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

#### 8.2. Exposure controls

##### 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:	base: several, catalyst: several
Odour:	characteristic

#### Test method

##### Changes in the physical state

Melting point/freezing point: not determined

Boiling point or initial boiling point and boiling range: not determined

Flash point: >100 °C DIN 51755

##### Flammability

Solid/liquid: not determined

Gas: not applicable

##### Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined

Upper explosion limits: not determined

Auto-ignition temperature: >400 °C DIN 51794

Decomposition temperature: >180 °C

pH-Value: not determined

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Viscosity / dynamic:  
(at 23 °C) 75000 mPa·s BROOKFIELD

Water solubility: The study does not need to be conducted because the substance is known to be insoluble in water.

**Solubility in other solvents**  
not determined

Partition coefficient n-octanol/water: not determined

Vapour pressure:  
(at 20 °C) <10 hPa

Density (at 20 °C): 1,25 g/cm<sup>3</sup> DIN 51757

Relative vapour density: not determined

### 9.2. Other information

#### Information with regard to physical hazard classes

Oxidizing properties  
The product is not: oxidising.

#### Other safety characteristics

Solid content: not determined

Evaporation rate: not determined

#### Further Information

## 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 : Acids, alkalis, alcohols, powdered metals or metal oxides with release of hydrogen.

### 10.4. Conditions to avoid

Temperatures > 150°C/ 302 °F.

### 10.5. Incompatible materials

No information available.

### 10.6. Hazardous decomposition products

In case of thermic decomposition hydrogen is released.

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 GB CLP Regulation

#### 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.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
8042-47-5	paraffin oil				
	oral	LD50 mg/kg	>5000	Rat	OECD
	dermal	LD50 mg/kg	>2000	Rabbit	OECD
	inhalation (4 h) vapour	LC50	>5 mg/l	Rat	OECD
540-97-6	Dodecamethylcyclohexasiloxane				
	oral	LD50 mg/kg	2000	Rat	
	dermal	LD50 mg/kg	2000	Rat	
541-02-6	Decamethylcyclopentasiloxane				
	oral	LD50 mg/kg	>24100	Rat	GESTIS
	dermal	LD50 mg/kg	>2000	Rabbit	OECD 402
	inhalation (4 h) vapour	LC50	8,67 mg/l	Rat	OECD 403
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

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

### 12.1. Toxicity

Harmful to aquatic life with long lasting effects.

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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)				
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

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The mixture contains the following substances fulfilling the PBT criteria according to UK REACH:

Dodecamethylcyclohexasiloxane.

The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:

Decamethylcyclopentasiloxane.

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.

Decamethylcyclopentasiloxane (D5) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D5 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 D5 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D5 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.

Dodecamethylcyclohexasiloxane (D6) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for very persistent and very bioaccumulative substances (vPvB) and was included in the candidate list of substances of very high concern (SVHC). According to our knowledge of the state of the art, however, D6 cannot be compared with known persistent, bioaccumulative and toxic (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 D6 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D6 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. 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.

### 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)**

<b><u>14.1. UN number or ID 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.



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#### Inland waterways transport (ADN)

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

#### Marine transport (IMDG)

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

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

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

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

Dodecamethylcyclohexasiloxane; Decamethylcyclopentasiloxane; Octamethylcyclotetrasiloxane

Restrictions on use (REACH, annex XVII):

Entry 70, Entry 75

2004/42/EC (VOC): 0 % (0,004 g/l)

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

##### Additional information

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

##### National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 3 - highly hazardous to water

##### Additional information

The mixture contains substances of very high concern (SVHC candidates):

Octamethylcyclotetrasiloxane (D4), CAS no. 556-67-2

Decamethylcyclopentasiloxane (D5), CAS no. 541-02-6

Dodecamethylcyclohexasiloxane (D6), CAS no. 540-97-6

#### 15.2. Chemical safety assessment

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

### SECTION 16: Other information

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#### 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  
VOC: Volatile Organic Compounds  
SVHC: Substance of Very High Concern  
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

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

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

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

H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H361f	Suspected of damaging fertility.
H372	Causes damage to organs (lung) through prolonged or repeated exposure if inhaled.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

#### 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 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.)*