

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

### **Cantex Silicone Roof Coating**

Version number: 2.0 Replaces version of: 22.03.2023 (1) Revision: 24.06.2024

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

#### 1.1 Product identifier

Trade name Registration number (REACH) **Cantex Silicone Roof Coating** 

not relevant (mixture)

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

Relevant identified uses

Paint Professional use

1.3 Details of the supplier of the safety data sheet

CANTEX DAKRENOVATIE B.V. Milrooijseweg 47 A 5258 KG Berlicum Netherlands

Telephone: +31 73 503 5843 e-mail: info@cantex.eu

#### 1.4 Emergency telephone number

Emergency information service

+31 73 503 5843 This number is only available during the following office hours: Mon-Fri 09:00 - 17:00

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

Code	Supplemental hazard information
EUH210	safety data sheet available on request

The most important adverse physicochemical, human health and environmental effects

The mixture contains a substance that was identified as a PBT (persistent, bioaccumulative and toxic). The mixture contains a substance that was identified as vPvB (very persistent and very bioaccumulative).

#### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

- signal word Not required.

- pictograms Not required.

- supplemental hazard information EUH210 Safety data sheet available on request.

#### 2.3 Other hazards

Results of PBT and vPvB assessment

Contains a PBT-substance at a concentration of  $\ge 0,1\%$ . Contains a vPvB-substance at a concentration of  $\ge 0,1\%$ . (Section 3)

#### Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ . (Section 11 & 12).



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### **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture).

#### 3.2 Mixtures

The product does not contain (other) ingredients which are classified according to present knowledge of the supplier and contribute to the classification of the product and hence require reporting in this section.

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes	Remarks
3- Aminopropyl(methyl) silsesquioxanes, eth- oxy-terminated	CAS No 128446-60-6 EC No 603-274-5	> 0,2 - < 1,5	Flam. Liq. 3 / H226 Skin Irrit. 2 / H315 Eye Irrit. 2 / H319			
Dodecamethylcyclo- hexasiloxane	CAS No 540-97-6 EC No 208-762-8	> 0,1 - < 0,5			PBT vPvB	

Notes

PBT: The substance was identified as a PBT (persistent, bioaccumulative and toxic)

vPvB: The substance was identified as a vPvB (very persistent and very bioaccumulative)

#### Remarks

All the percentages given are percentages by weight unless stated otherwise. For full text of H-phrases: see SECTION 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### General notes

Do not leave affected person unattended. Remove victim out of the danger area. In case of unconsciousness place person in the recovery position. Never give anything by mouth. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following inhalation

Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician.

#### Following skin contact

Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

#### Following eye contact

Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

#### Following ingestion

Rinse mouth with water (only if the person is conscious). Call a doctor if you feel unwell.

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

Symptoms and effects are not known to date.

## **4.3** Indication of any immediate medical attention and special treatment needed None.



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#### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

#### Suitable extinguishing media

Water spray; Dry extinguishing powder; Carbon dioxide (CO2); Co-ordinate firefighting measures to the fire surroundings.

Unsuitable extinguishing media

Water jet.

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

#### Hazardous combustion products

During fire hazardous fumes/smoke could be produced. Carbon monoxide (CO). Carbon dioxide (CO2).

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

Self-contained breathing apparatus (EN 133). Standard protective clothing for firefighters.

#### **SECTION 6: Accidental release measures**

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

#### For non-emergency personnel

Remove persons to safety. Ventilate affected area.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Use personal protective equipment as required.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

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

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill Wipe up with absorbent material (e.g. cloth, fleece).

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.



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#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

#### Recommendations

- measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

#### Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

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

Managing of associated risks

- flammability hazards

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge.

- incompatible substances or mixtures

Keep away from alkalis, oxidising substances, acids.

#### Control of effects

Protect against external exposure, such as

High temperatures. UV-radiation/sunlight.

## Consideration of other advice Keep in a cool, well-ventilated place.

- packaging compatibilities Keep only in original container.

#### 7.3 Specific end use(s)

There is no additional information.

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

National limit values

No information available.

#### Relevant DNELs/DMELs/PNECs and other threshold levels

Relevant DNELs of components of the mixture								
Name of sub- stance	CAS No	End- point	Threshold level	Protection goal, route of expos- ure	Used in	Exposure time		
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	11 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects		
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	2,7 mg/m <sup>3</sup>	human, inhalatory	consumer (private households)	chronic - systemic effects		
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	1,7 mg/kg bw/day	human, oral	consumer (private households)	chronic - systemic effects		
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	1,7 mg/kg bw/day	human, oral	consumer (private households)	acute - systemic ef- fects		



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Relevant DNELs of components of the mixture								
Name of sub- stance	CAS No	End- point	Threshold level	Protection goal, route of expos- ure	Used in	Exposure time		
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	1,22 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local ef- fects		
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	6,1 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - local effects		
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	0,3 mg/m <sup>3</sup>	human, inhalatory	consumer (private households)	chronic - local ef- fects		
Dodecamethylcyclo- hexasiloxane	540-97-6	DNEL	1,5 mg/m <sup>3</sup>	human, inhalatory	consumer (private households)	acute - local effects		

#### Relevant PNECs of components

	•					
Name of sub- stance	CAS No	End- point	Threshold level	Organism	Environmental compartment	Exposure time
Dodecamethylcyclo- hexasiloxane	540-97-6	PNEC	1 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Dodecamethylcyclo- hexasiloxane	540-97-6	PNEC	3,77 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single instance)
Dodecamethylcyclo- hexasiloxane	540-97-6	PNEC	13,5 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single instance)
Dodecamethylcyclo- hexasiloxane	540-97-6	PNEC	1,35 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single instance)

#### 8.2 Exposure controls

#### Appropriate engineering controls

General ventilation. Provide eyewash stations and safety showers at the workplace.

Individual protection measures (personal protective equipment)

Eye/face protection

Use safety goggle with side protection (EN 166).

Skin protection

Protective clothing (EN 340 & EN ISO 13688).

Hand protection



Wear suitable gloves. Check leak-tightness/impermeability prior to use. 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. Chemical protection gloves are suitable, which are tested according to EN 374. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- type of material

NBR: acrylonitrile-butadiene rubber, Nitrile rubber, CR: chloroprene (chlorobutadiene) rubber



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#### - material thickness

Use gloves with a minimum material thickness:  $\geq$  0,38 mm.

#### - other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection. Full face mask/half mask/quarter mask (EN 136/140). Type: ABEK-P2 (combined filters against gases, vapours and particles, colour code: Brown/Grey/Yellow/Green/White).

#### Environmental exposure controls

Take appropriate precautions to avoid uncontrolled release into the environment. Keep away from drains, surface and ground water.

#### **SECTION 9: Physical and chemical properties**

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

Physical state	liquid
Colour	white
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	LEL: UEL: not determined
Flash point	>100 °C
Auto-ignition temperature	not determined
Decomposition temperature	no data available
pH (value)	7
Kinematic viscosity	17.391 <sup>mm²</sup> /s
Solubility	not determined

Partition coefficient n-octanol/water (log value)	this information is not available

Vapour pressure	not determined
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#### Density and/or relative density

Density	1,25 <sup>g</sup> / <sub>cm<sup>3</sup></sub>
Relative vapour density	information on this property is not available

Particle characteristics

not relevant (liquid)

#### 9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics	there is no additional information

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

#### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

#### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

#### 10.5 Incompatible materials

Oxidisers.

#### **10.6 Hazardous decomposition products**

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

#### **SECTION 11: Toxicological information**

#### Information on hazard classes as defined in Regulation (EC) No 1272/2008

Test data are not available for the complete mixture.

#### Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

#### Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

#### Acute toxicity

Shall not be classified as acutely toxic.

11.1



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Acute toxicity of components								
Name of substance	CAS No	Exposure route	Endpoint	Value	Species			
Dodecamethylcyclohexasiloxane	540-97-6	oral	LD50	>2.000 <sup>mg</sup> / <sub>kg</sub>	rat			
Dodecamethylcyclohexasiloxane	540-97-6	dermal	LD50	>2.000 <sup>mg</sup> / <sub>kg</sub>	rat			

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

#### Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

#### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

#### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

#### Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

#### Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

#### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

#### Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

Endocrine Disruptor lists								
Name of substance	CAS No	Endocrine dis- ruptor for human health	Endocrine dis- ruptor for the en- vironment	Listed in				
Dodecamethylcyclohexasiloxane	540-97-6	yes		List II				

#### Legend List II

Substances under evaluation for endocrine disruption under an EU legislation

### Other information

There is no additional information.



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osure time

### **SECTION 12: Ecological information**

#### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposur time
Dodecamethylcyclohexasiloxane	540-97-6	NOEC	≥2 <sup>µg</sup> / <sub>l</sub>	algae	72 h

Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Dodecamethylcyclohexasiloxane	540-97-6	EC50	>100 <sup>mg</sup> / <sub>l</sub>	microorganisms	3 h

#### 12.2 Persistence and degradability

Data are not available.

#### 12.3 **Bioaccumulative potential**

Data are not available.

#### 12.4 Mobility in soil

Data are not available.

#### 12.5 Results of PBT and vPvB assessment

Contains a vPvB-substance at a concentration of  $\ge 0,1\%$ . Contains a PBT-substance at a concentration of  $\ge 0,1\%$ .

#### **Endocrine disrupting properties** 12.6

Contains an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

Endocrine Disruptor lists				
Name of substance	CAS No	Endocrine dis- ruptor for human health	Endocrine dis- ruptor for the en- vironment	Listed in
Dodecamethylcyclohexasiloxane	540-97-6	yes		List II

Legend List II

Substances under evaluation for endocrine disruption under an EU legislation

#### 12.7 Other adverse effects

Data are not available.



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#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

#### Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment.

#### Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

#### **SECTION 14: Transport information**

14.1	UN number or ID number	not subject to transport regulations
14.2	UN proper shipping name	not relevant
14.3	Transport hazard class(es)	none
14.4	Packing group	not assigned
14.5	Environmental hazards	non-environmentally hazardous acc. to the dangerous goods regulations

- **14.6** Special precautions for user There is no additional information.
- **14.7 Maritime transport in bulk according to IMO instruments** No data available.

#### Additional information for each of the UN Model Regulations

## Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - additional information

Not subject to ADR, RID and ADN.

### International Maritime Dangerous Goods Code (IMDG) - additional information Not subject to IMDG.

#### International Civil Aviation Organization (ICAO-IATA/DGR) - additional information Not subject to ICAO-IATA.

#### **SECTION 15: Regulatory information**

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

### **Restrictions according to REACH, Annex XVII**

Name	Name acc. to inventory	Restriction	No
3-Aminopropyl(methyl) silsesquioxanes, eth- oxy-terminated	this product meets the criteria for classification in accordance with Regulation No 1272/2008/ EC	R3	3
3-Aminopropyl(methyl) silsesquioxanes, eth- oxy-terminated	flammable / pyrophoric	R40	40



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	Name	Name acc. to inventory	Restriction	No
3-Ami	nopropyl(methyl) silsesquioxanes, eth- oxy-terminated	substances in tattoo inks and permanent make-up	R75	75
Legend R3	trays, - tricks and jokes, - games for one or more participants, or an 2. Articles not complying with paragraph 1 3. Shall not be placed on the market if they — can be used as fuel in decorative oil lam — present an aspiration hazard and are lal 4. Decorative oil lamps for supply to the ge on Decorative oil lamps for supply to the ge on Decorative oil lamps (EN 14059) adopted 5. Without prejudice to the implementation and mixtures, suppliers shall ensure, befor (a) lamp oils, labelled with H304, intended lamps filled with this liquid out of the reach lamps – may lead to life-threatening lung di (b) grill lighter fluids, labelled with H304, in as follows: 'Just a sip of grill lighter fluid ma (c) lamps oils and grill lighters, labelled witt exceeding 1 litre by 1 December 2010.'; 1. Shall not be used, as substance or as m general public for entertainment and decor - metallic glitter intended mainly for decorar - artificial snow and frost, - 'whoopee' cushions, - silly string aerosols, - imitation excrement, - horns for parties, - decorative flakes and foams, - artificial cobwebs, - stink bombs. 2. Without prejudice to the application of o	contain a colouring agent, unless required for fiscal re- ips for supply to the general public, and belled with H304. neral public shall not be placed on the market unless the d by the European Committee for Standardisation (CI of other Union provisions relating to the classification, e the placing on the market, that the following requiren for supply to the general public are visibly, legibly and of children"; and, by 1 December 2010, "Just a sip of amage"; tended for supply to the general public are legibly and ay lead to life threatening lung damage'; n H304, intended for supply to the general public are public are public instrures in aerosol dispensers where these aerosol disp ative purposes such as the following:	nental aspects, easons, or perfume, or both they conform to the Europea EN). labelling and packaging of nents are met: indelibly marked as follows lamp oil – or even sucking t indelibly marked by 1 Dece packaged in black opaque of pensers are intended for su	, if they: an Standard substance s: "Keep the wick of ember 2010 containers r apply to the

and indefinity with:
'For professional users only'.
By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/ 324/EEC (2).
The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.



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1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight; (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B,

the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator;

(ii) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(i) "Rinse-off products";
 (ii) "Not to be used in products applied on mucous membranes";

(iii) "Not to be used in eye products"

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;

(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix. 2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's

skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or as upplication of that new or revised classification.
6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of t

or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(b) a reference number to uniquely identify the batch;

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a com-mon ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that in-gredient does not need to be marked in accordance with this Regulation;

(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1; (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;

(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008. The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the

a. Mixtures that do not contain the statement "Mixture for use in tations for use pursuant to this paragraph.
a. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.
b. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).
c. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattoo-ing purposes, or to the use of a mixture for tattoo-ing purposes.

ing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of



according to Regulation (EC) No. 1907/2006 (REACH)

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Legend

Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

### List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

Substance of Very High Concern (SVHC)

Name acc. to inventory	CAS No	Listed in	Remarks
dodecamethylcyclohexasiloxane	540-97-6	Candidate list	PBT A57d vPvB A57e

Legend

Candidate list Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV PBT A57d Persistent, Bioaccumulative and Toxic (article 57d)

vPvB A57e Very Persistent and very Bioaccumulative (article 57e)

### **Seveso Directive**

2012/18/EU (Seveso III)					
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the applica- tion of lower and upper-tier requirements	Notes		
	not assigned				

## Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

None of the ingredients are listed.

#### Water Framework Directive (WFD)

None of the ingredients are listed.

# Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

None of the ingredients are listed.

#### Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

#### National regulations (Netherlands)

#### SZW-lijst CMR effects

None of the ingredients are listed.

List of Substances of Very High Concern, Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

List of Substances of Very High Concern (ZZS-lijst)				
Name acc. to inventory	CAS No	Dust class for air emissions	Remarks	Emission limit value
dodecamethylcyclohexasiloxane	540-97-6	MVP 1	rem-141	0,05 mg/Nm3
Leneral		•		•

Legend

rem-141 Berekend als Sb

#### 15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.



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#### **SECTION 16: Other information**

### Indication of changes (revised safety data sheet)

Complete revision of the safety data sheet.

#### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the In- ternational Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
DGR	Dangerous Goods Regulations (see IATA/DGR)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
Flam. Liq.	Flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
ΙΑΤΑ	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a spe- cified time interval
LEL	Lower explosion limit (LEL)
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration



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Abbr.	Descriptions of used abbreviations
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Re ing the International carriage of Dangerous goods by Rail)	
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
SVHC	Substance of Very High Concern
UEL	Upper explosion limit (UEL)
vPvB	Very Persistent and very Bioaccumulative

#### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

#### **Classification procedure**

Physical and chemical properties: The classification is based on tested mixture. Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

#### List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text			
H226	Flammable liquid and vapour.			
H315	Causes skin irritation.			
H319	Causes serious eye irritation.			

#### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.