

Safety Data Sheets

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Silcofix

Article no.: No. 93801-3

Revised on: 15.05.2023


Version: 3.0 Replaced version:2.0



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

1.1	Product identifier	Silcofix Article no.:93801-3
1.2	Relevant identified uses of the substance or mixture and uses which are not recommended	
1.2.1	Relevant uses medical device:	Silcofix
1.2.2	Uses that are not recommended:	None known
1.3	Details of the supplier providing the safety data sheet	Dr. Hinz Dental Vertriebsgesellschaft mbH & Co. KG Friedrich der Große 64 44628 Herne GERMANY Phone: + 49 (0) 23 23 / 59 34 20 Fax : + 49 (0) 23 23 / 59 34 29 E-Mail: qm@dhug.de
1.4	Emergency number	Contact: Dr. P. Hinz Phone: + 49 17 51 83 41 34

SECTION 2: Possible dangers

2.1	Classification of the substance or mixture The most important adverse physicochemical effects, effects on human health and the environment Product is flammable and can be ignited by potential ignition sources.	
2.1.1	Classification according to (EC) Regulation 1272/2008 as amended. Hazard categories: Flammable liquid: Flam. Liq. 2 Serious eye damage/eye irritation: Eye Irrit. 2 Specific target organ toxicity - single exposure: STOT SE 3 Hazard Statements: Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness.	
2.2	Labelling elements Additional information:	Signal word Danger - Pictograms GHS02, GHS07  Hazard statements H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. Precautionary statements

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		<p>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Do not smoke.</p> <p>P261 Avoid breathing dust/fume/gas/mist/vapor/aerosol.</p> <p>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P337+P313 If eye irritation persists: Get medical advice/attention.</p> <p>P403+P235 Store in a well-ventilated place. Keep cool.</p> <p>P501 Dispose of contents/container to local/regional/national/international regulations.</p> <p>Special labelling of certain mixtures Labelling of packages where the contents do not exceed 125 ml Signal word: Danger Pictograms:</p>
2.3	Other dangers	In use, may form flammable/explosive vapor/air mixture. The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, Annex XIII.

SECTION 3: Composition / Information on ingredients

3.1	Chemical characterisation	Ethyl acetate, hydrocarbons, C9-C11, n-alkanes, iso-alkanes, cyclic compounds, aromatics (< 2 %), 2-propanol; isopropyl alcohol; isopropanol																																													
3.1.1	Dangerous ingredients	<table border="1"> <thead> <tr> <th>CAS No</th> <th>Chemical name</th> <th>Quantity</th> </tr> </thead> <tbody> <tr> <td></td> <td>EC No</td> <td>Index No</td> </tr> <tr> <td></td> <td>REACH No</td> <td></td> </tr> <tr> <td colspan="3">GHS Classification</td> </tr> <tr> <td>141-78-6</td> <td>ethyl acetate</td> <td>40 - 80 %</td> </tr> <tr> <td></td> <td>205-500-4</td> <td>607-022-00-5</td> </tr> <tr> <td></td> <td></td> <td>01-2119475103-46</td> </tr> <tr> <td></td> <td colspan="2">Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336 EUH066</td> </tr> <tr> <td>64742-48-9</td> <td>Hydrocarbons, C9-C11, n-alkane, iso-alkane, cyclic compounds, aromatics (< 2 %)</td> <td>15 - < 20 %</td> </tr> <tr> <td></td> <td>919-857-5</td> <td>01-2119463258-33</td> </tr> <tr> <td></td> <td colspan="2">Flam. Liq. 3, STOT SE 3, Asp. Tox. 1; H226 H336 H304 EUH066</td> </tr> <tr> <td>67-63-0</td> <td>propan-2-ol; isopropyl alcohol; isopropanol</td> <td>10 - 30 %</td> </tr> <tr> <td></td> <td>200-661-7</td> <td>603-117-00-0</td> </tr> <tr> <td></td> <td></td> <td>01-2119457558-25</td> </tr> <tr> <td></td> <td colspan="2">Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336</td> </tr> </tbody> </table> <p>Full text of H and EUH statements: see section 16. Labelling for contents according to Regulation (EC) No 648/2004 15 % - < 30 % aliphatic hydrocarbons. Further Information Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)</p>	CAS No	Chemical name	Quantity		EC No	Index No		REACH No		GHS Classification			141-78-6	ethyl acetate	40 - 80 %		205-500-4	607-022-00-5			01-2119475103-46		Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336 EUH066		64742-48-9	Hydrocarbons, C9-C11, n-alkane, iso-alkane, cyclic compounds, aromatics (< 2 %)	15 - < 20 %		919-857-5	01-2119463258-33		Flam. Liq. 3, STOT SE 3, Asp. Tox. 1; H226 H336 H304 EUH066		67-63-0	propan-2-ol; isopropyl alcohol; isopropanol	10 - 30 %		200-661-7	603-117-00-0			01-2119457558-25		Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336	
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Section 4: First aid measures

4.1	Description of the first aid measures	
	General notes	In case of accident or if you feel unwell, seek medical advice immediately (if possible, show operating instructions or safety data sheet). if possible). Immediately remove contaminated, soaked clothing. First aiders: Pay attention to self-protection

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	Inhalation:	Remove the person to fresh air and ensure unobstructed breathing . In case of irritation of the respiratory tract doctor.
	Eye contact:	Rinse gently with water for a few minutes. If possible, remove any contact lenses
	Skin contact:	Immediately remove soiled, saturated clothing. Wash off with plenty of water. In case of skin irritation consult a doctor.
	Ingestion:	Rinse mouth thoroughly with water. Allow to drink plenty of water in small sips (dilution effect). DO NOT induce vomiting. Never give anything by mouth to an unconscious person or in case of Never administer by mouth to an unconscious person or if convulsions occur. If symptoms occur or in case of doubt, seek medical advice. in case of doubt.
4.2	Most important symptoms and effects, both acute and delayed:	There is no information available.
4.3	Indications for immediate medical help or special treatment	
	Dangers:	This product is not expected to be harmful under normal use and proper personal hygiene.
	Treatment:	Symptomatic treatment.

SECTION 5: Fire-fighting measures

5.1	General fire hazards	Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.
	Extinguishing agent Suitable extinguishing media	Carbon dioxide (CO ₂). Dry extinguishing agent. alcohol-resistant foam. For large fires and large quantities: Water spray.
	Unsuitable extinguishing media:	Water full jet.
5.2	Special hazards arising from the substance or mixture:	In case of fire may evolve: Gases/vapors, irritant. Carbon monoxide. Carbon dioxide (CO ₂).
5.3	Advice for firefighters Advice for firefighters:	In case of fire: Use self-contained breathing apparatus. Do not inhale explosion and fire gases inhale.
	Special protective equipment for fire fighting:	Collect contaminated extinguishing water separately. Do not allow to enter drains or bodies of water. For Use water spray to protect persons and to cool containers in the danger area. In case of large fires and large quantities: Clear surrounding area. Because of danger of explosion fight fire from a distance. from a distance.

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SECTION 6: Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures:	Move persons to safety. Remove all sources of ignition. Ventilate the affected area. Do not breathe gas/vapor/aerosol. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. (See Section 8.)
6.2	Environmental protection measures:	Do not allow to enter drains or waterways. Danger of explosion! Cover sewage system. Prevent expansion over a wide area (e.g. by diking or oil booms). In case of gas leakage or In the event of gas leakage or penetration into water, soil or sewage system, notify the relevant authorities.
6.3	Methods and material for retention and cleaning:	Absorb with liquid-binding material (sand, diatomaceous earth, acid binders, universal binders). Ventilate the ventilate the affected area. Treat the absorbed material according to the section Disposal. Thoroughly clean contaminated objects and surfaces in compliance with environmental regulations .
6.4	Reference to other sections:	Safe handling: see section 7 Personal protective equipment: see section 8 Disposal: see section 13

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Section 7: Handling and storage:

7.1	Protective measures for safe handling:	<p>Provide adequate ventilation and spot extraction at critical points . Do not inhale gas/vapor/aerosol. Avoid contact with skin, eyes and clothing.</p> <p>Wear suitable protective clothing when working. (See section 8.)</p> <p>Information for safe handling</p> <p>Keep away from sources of ignition - Do not smoke. Take measures against electrostatic charges. In the</p> <p>Flammable vapors may accumulate in the vapor space of closed systems. During use formation of explosive/flammable vapor/air mixtures possible. Heating leads to pressure increase and risk of bursting.</p> <p>Information on fire and explosion protection</p> <p>Protective and hygienic measures: See section 8.)</p>
	Notes on fire and explosion protection:	<p>Keep container tightly closed and store in a cool, well-ventilated place. Protect from direct direct sunlight.</p> <p>Ensure sufficient ventilation of the storage room.</p> <p>Ensure that leakages can be collected (e.g. drip pans or collecting surfaces).</p>
7.2	Conditions for safe storage taking into account incompatibilities:	<p>Do not store together with: Gas. Explosives. Flammable solids. Spontaneously combustible (pyrophoric) liquid and solid substances. Self-heating substances or mixtures. Substances and mixtures which, in contact flammable gases in contact with water. Flammable (oxidizing) liquid substances. Flammable (Oxidizing) solids. Ammonium nitrate. Self-reactive substances and mixtures. Organic peroxides. Non-flammable toxic substances. Radioactive substances. Infectious substances.</p>
	Storage stability:	<p>Keep the packaging dry and tightly closed to avoid contamination and absorption of moisture.</p> <p>avoid.</p> <p>Protect against: UV radiation/sunlight. Heat. Humidity Frost.</p> <p>Storage temperature: 15-25°C</p>
	Storage class:	according to TRGS 510: 3 (Flammable liquids)
7.3	Specific end uses:	according to TRGS 510: 3 (Flammable liquids)

SECTION 8: Exposure controls/personal protective equipment

8.1	Parameters to be monitored Occupational exposure limit values	
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Occupational exposure limits (TRGS 900)

CAS No	Substance	ppm	mg/m ³	F/m ³	Category	Origin
141-78-6	Ethyl acetate	200	-		TWA (8 h)	WEL
		400	-		STEL (15 min)	WEL
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
		500	1250		STEL (15 min)	WEL

DNEL/DMEL values

CAS No	Substance	DNEL type	Exposure route	Effect	Value
141-78-6	ethyl acetate	Worker DNEL, long-term	dermal	systemic	63 mg/kg bw/day
		Worker DNEL, acute	inhalation	systemic	1468 mg/m ³
		Worker DNEL, acute	inhalation	local	1468 mg/m ³
		Worker DNEL, long-term	inhalation	systemic	734 mg/m ³
		Worker DNEL, long-term	inhalation	local	734 mg/m ³
		Consumer DNEL, long-term	oral	systemic	4,5 mg/kg bw/day
		Consumer DNEL, long-term	dermal	systemic	37 mg/kg bw/day
		Consumer DNEL, acute	inhalation	local	734 mg/m ³
		Consumer DNEL, acute	inhalation	systemic	734 mg/m ³
		Consumer DNEL, long-term	inhalation	lokal	367 mg/m ³
67-63-0	propan-2-ol; isopropyl alcohol; isopropanol	Worker DNEL, long-term	inhalation	systemic	500 mg/m ³
		Consumer DNEL, long-term	inhalation	systemic	89 mg/m ³
		Worker DNEL, long-term	dermal	systemic	888 mg/kg bw/day
		Consumer DNEL, long-term	oral	systemic	26 mg/kg bw/day
		Consumer DNEL, long-term	dermal	systemic	319 mg/kg KG/day
		Consumer DNEL, long-term	dermal	systemic	319 mg/kg KG/day

PNEC values

CAS No	Substance	Environmental compartment	Value		
141-78-6	ethyl acetate	Freshwater	0,26 mg/l		
		Freshwater (intermittent releases)	1,65 mg/l		
		Marine water	0,026 mg/l		
		Freshwater sediment	1,25 mg/kg		
		Marine sediment	0,125 mg/kg		
		Secondary poisoning	200 mg/kg		
		Micro-organisms in sewage treatment plants (STP)	650 mg/l		
		Soil	0,24 mg/kg		
		67-63-0	propan-2-ol; isopropyl alcohol; isopropanol	Freshwater	140,9 mg/l
				Marine water	140,9 mg/l
Freshwater sediment	552 mg/kg				
Marine sediment	552 mg/kg				
Secondary poisoning	160 mg/kg				
Soil	28 mg/kg				

Biological limit values

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8.2	Exposure controls Suitable engineering controls:	Provide adequate ventilation and spot extraction at critical points.
	Individual protective measures, for example personal protective equipment	
	General information:	<p>The usual precautions when handling chemicals must be observed .</p> <p>Keep away from food, beverages and animal feed.</p> <p>Always close containers tightly after removing product. Do not eat, drink, smoke in the workplace,</p> <p>snort. Wash hands before breaks and at the end of work. Preventive skin protection with</p> <p>skin protection ointment. Remove contaminated clothing and wash before wearing again.</p>
	Eye/face protection:	Recommended eye protection brands: Tight-fitting safety goggles. (DIN EN 166)
	Skin protection Hand protection:	<p>In case of prolonged or often repeated skin contact: Wear suitable protective gloves.</p> <p>Suitable material: butyl rubber.</p> <p>Thickness of glove material: 0.5 mm.</p> <p>Breakthrough time: >= 480 min. Penetration time (maximum wearing time): ~ 120 min. (estimated)</p> <p>If gloves are intended for reuse, clean gloves before removal and store in a well ventilated area .</p> <p>Check for tightness / impermeability before use.</p> <p>It is recommended to clarify the chemical resistance of the above mentioned protective gloves for specific</p> <p>applications with the glove manufacturer.</p> <p>The gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the resulting standard</p> <p>and the resulting standard EN374.</p>
Other:	<p>Wear flame-resistant/flame-retardant clothing.</p> <p>Minimum standards for protective measures when handling working substances are listed in TRGS 500.</p>	
Respiratory protection:	<p>Respiratory protection is not required when used properly and under normal conditions .</p> <p>Respiratory protection is required for:</p>	

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	<p>Aerosol generation/formation</p> <p>Exceeding of limit value</p> <p>Insufficient ventilation.</p> <p>Suitable respiratory protection device: Combination filter device (EN 14387) Filter type: A/P1-3</p> <p>It is essential that the respiratory protection filter class is adapted to the maximum pollutant concentration (gas/vapor/aerosol/particles) that may be generated when handling the product. If the concentration is exceeded</p> <p>isolation equipment must be used! The wearing time limitations according to GefStoffV in conjunction with the rules for the</p> <p>use of respiratory protective equipment (BGR 190) must be observed.</p>
Hygiene measures:	<p>The usual precautions when handling chemicals must be observed .</p> <p>Keep away from food, beverages and animal feed.</p> <p>Always close containers tightly after removing product. Do not eat, drink, smoke in the workplace,</p> <p>snort. Wash hands before breaks and at the end of work. Preventive skin protection with</p> <p>skin protection ointment. Remove contaminated clothing and wash before wearing again.</p>
Limitation and monitoring of environmental exposure:	<p>Do not allow uncontrolled release of product into the environment.</p>

SECTION 9: Physical and chemical properties

9.1	Information on the basic physical and chemical properties	
	Parameter	Wert
	State of aggregation	liquid.
	Colour	Not determined
	Smell	characteristic
	Melting point/freezing point	inapplicable
	Boiling point or initial boiling point and boiling range	inapplicable
	Flammability	Not determined
	Lower explosion limit upper explosion limit	Not determined

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	Flash point	Not determined
	Ignition temperature	Not determined
	Decomposition temperature	Not determined
	pH value	Not determined
	Kinematic viscosity	Not determined
	Solubility	Water solubility: miscible.
	Partition coefficient n-octanol/water (log value)	Not determined
	Vapour pressure	Not determined
	Density and/or specific gravity	Not determined
	Relative vapour density	Not determined
	Particle properties	Not determined
9.2.	Other information Not determined	

SECTION 10: Stability and reactivity

10.1	Reactivity	There is no information available.
10.2	Chemical stability	The mixture is chemically stable under the recommended storage, use and temperature conditions.
10.3	Possibility of hazardous reactions	See chapter 10.5.
10.4	Conditions to avoid	Protect from heat. Risk of ignition! Can form explosive/flammable vapor/air mixtures during use. Heating leads to pressure increase and bursting hazard.
10.5	Incompatible materials	Substances to avoid: Oxidizing agents, strong. Reducing agents, strong. Strong acid. strong alkali.
10.6	Decomposition products	In case of fire may evolve: Gases/vapors, irritant. Carbon monoxide. Carbon dioxide (CO ₂).

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SECTION 11: Toxicological data

11.1

Information on hazard classes within the meaning of Regulation (EC) No 1272/2008

acute toxicity

CAS No	Chemical name				
	Exposure route	Dosis	Species	Source	Method
141-78-6	ethyl acetate				
	dermal	LD50 >20000 mg/kg	Rabbit.	ECHA Dossier	
64742-48-9	Hydrocarbons, C9-C11, n-alkane, iso-alkane, cyclic compounds, aromatics (< 2 %)				
	oral	LD50 8000 mg/kg	Rat	MSDS external	
	dermal	LD50 4000 mg/kg	Rat	MSDS external	
67-63-0	2-Propanol; Isopropylalkohol; Isopropanol				
	oral	LD50 >5000 mg/kg	Rat	ECHA Dossier	
	dermal	LD50 >5000 mg/kg	Rabbit.	ECHA Dossier	

Corrosive/irritant effect on the skin

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

Serious eye damage/irritation

Causes severe eye irritation.

Sensitisation of the respiratory tract/skin

Based on available data, the classification criteria are not met. Ethyl Acetate:
 In vitro mutagenicity: Method: OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test); Result Negative. Literature reference: ECHA dossier; No evidence of carcinogenicity in humans available.
 Literature reference: ECHA dossier; Reproductive toxicity: Method: other guideline: US EPA Health Effects Testing Guidelines 40 CFR Part 798.2450 ; Species: Rat ;Exposure duration: 94 d. Result: NOAEL = 1500 ppm ; Reference: ECHA Dossier
 Hydrocarbons, C9-C11, n-alkanes, iso-alkanes, cyclic compounds, aromatics (< 2%):
 In vitro mutagenicity: method: OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test) ; result: negative. Literature reference: ECHA Dossier;
 Carcinogenicity: Method: (dermal.) OECD Guideline 451 (Carcinogenicity Studies); Species: Mouse; Test duration: 2 years; Result: negative. Literature reference: ECHA Dossier; Reproductive Toxicity: Method: OECD Guideline 416 (Two-Generation Reproduction Toxicity Study); Species: Rat; Result: NOAEL >= 20000 mg/kg; Reference: ECHA dossier.
 Developmental toxicity /Teratogenicity: Method: OECD Guideline 414 (Prenatal Developmental Toxicity Study); Species: Rat Result: NOAEL = 239000 mg/kg; Reference: ECHA Dossier
 2-Propanol; Isopropyl alcohol; Isopropanol (CAS No.: 67-63-0):
 OECD Guideline 471 (Bacterial Reverse Mutation Assay) = negative, AllgK267153: ECHA Dossier; OECD.

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		<p>Guideline 474 (Mammalian Erythrocyte Micronucleus Test) = negative, Reference: ECHA dossier; None. No evidence of carcinogenicity in humans, reference: ECHA dossier; Reproductive toxicity: Method: OECD Guideline 415 (One-Generation Reproduction Toxicity Study); Species: rat ; Result: NOAEL = 853 mg/kg; Reference: ECHA dossier; Developmental toxicity / teratogenicity: Method: (oral.) OECD Guideline 414 (Prenatal Developmental Toxicity Study) ; Species: rabbit ; Result: NOAEL = 480 mg/kg; Reference: ECHA Dossier</p>
<p>Germ cell mutagenicity</p>		<p>Based on available data, the classification criteria are not met. Ethyl Acetate:</p> <p>In vitro mutagenicity: Method: OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test); Result Negative. Literature reference: ECHA dossier; No evidence of carcinogenicity in humans available.</p> <p>Literature reference: ECHA dossier; Reproductive toxicity: Method: other guideline: US EPA Health Effects</p> <p>Testing Guidelines 40 CFR Part 798.2450 ; Species: Rat ; Exposure duration: 94 d. Result: NOAEL = 1500 ppm ; Reference: ECHA Dossier</p> <p>Hydrocarbons, C9-C11, n-alkanes, iso-alkanes, cyclic compounds, aromatics (< 2%):</p> <p>In vitro mutagenicity: method: OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test) ; result: negative. Literature reference: ECHA Dossier; Carcinogenicity: Method: (dermal.) OECD Guideline 451 (Carcinogenicity Studies); Species: Mouse; Test duration: 2 years; Result: negative. Literature reference: ECHA Dossier; Reproductive Toxicity: Method: OECD Guideline 416 (Two-Generation Reproduction Toxicity Study); Species: Rat; Result: NOAEL >= 20000 mg/kg; Reference: ECHA dossier.</p> <p>Developmental toxicity /Teratogenicity: Method: OECD Guideline 414 (Prenatal Developmental Toxicity Study); Species: Rat Result: NOAEL = 239000 mg/kg; Reference: ECHA Dossier</p>

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		<p>2-Propanol; Isopropyl alcohol; Isopropanol (CAS No.: 67-63-0):</p> <p>OECD Guideline 471 (Bacterial Reverse Mutation Assay) = negative, AllgK267153: ECHA Dossier; OECD.</p> <p>Guideline 474 (Mammalian Erythrocyte Micronucleus Test) = negative, Reference: ECHA dossier; None.</p> <p>No evidence of carcinogenicity in humans, reference: ECHA dossier; Reproductive toxicity:</p> <p>Method: OECD Guideline 415 (One-Generation Reproduction Toxicity Study); Species: rat ; Result:</p> <p>NOAEL = 853 mg/kg; Reference: ECHA dossier; Developmental toxicity / teratogenicity: Method: (oral.)</p> <p>OECD Guideline 414 (Prenatal Developmental Toxicity Study) ; Species: rabbit ; Result: NOAEL = 480 mg/kg; Reference: ECHA Dossier</p>
	Carcinogenicity	<p>Based on available data, the classification criteria are not met.Ethyl Acetate:</p> <p>In vitro mutagenicity: Method: OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test); Result Negative. Literature reference: ECHA dossier; No evidence of carcinogenicity in humans available.</p> <p>Literature reference: ECHA dossier; Reproductive toxicity: Method: other guideline: US EPA Health Effects</p> <p>Testing Guidelines 40 CFR Part 798.2450 ; Species: Rat ;Exposure duration: 94 d. Result: NOAEL = 1500 ppm ; Reference: ECHA Dossier</p> <p>Hydrocarbons, C9-C11, n-alkanes, iso-alkanes, cyclic compounds, aromatics (< 2%):</p> <p>In vitro mutagenicity: method: OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test) ; result:</p> <p>negative. Literature reference: ECHA Dossier; Carcinogenicity: Method: (dermal.) OECD Guideline 451 (Carcinogenicity Studies); Species: Mouse; Test duration: 2 years; Result: negative. Literature reference: ECHA</p>

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Version: 3.0 Replaced version:2.0



		<p>Dossier; Reproductive Toxicity: Method: OECD Guideline 416 (Two-Generation Reproduction Toxicity Study);</p> <p>Species: Rat; Result: NOAEL \geq 20000 mg/kg; Reference: ECHA dossier.</p> <p>Developmental toxicity /Teratogenicity: Method: OECD Guideline 414 (Prenatal Developmental Toxicity Study);</p> <p>Species: Rat Result: NOAEL = 239000 mg/kg; Reference: ECHA Dossier</p> <p>2-Propanol; Isopropyl alcohol; Isopropanol (CAS No.: 67-63-0):</p> <p>OECD Guideline 471 (Bacterial Reverse Mutation Assay) = negative, AllgK267153: ECHA Dossier; OECD.</p> <p>Guideline 474 (Mammalian Erythrocyte Micronucleus Test) = negative, Reference: ECHA dossier; None.</p> <p>No evidence of carcinogenicity in humans, reference: ECHA dossier; Reproductive toxicity:</p> <p>Method: OECD Guideline 415 (One-Generation Reproduction Toxicity Study); Species: rat ; Result:</p> <p>NOAEL = 853 mg/kg; Reference: ECHA dossier; Developmental toxicity / teratogenicity: Method: (oral.)</p> <p>OECD Guideline 414 (Prenatal Developmental Toxicity Study) ; Species: rabbit ; Result: NOAEL = 480 mg/kg; Reference: ECHA Dossier</p>
Reproductive toxicity		<p>Based on available data, the classification criteria are not met.Ethyl Acetate:</p> <p>In vitro mutagenicity: Method: OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test); Result Negative. Literature reference: ECHA dossier; No evidence of carcinogenicity in humans available.</p> <p>Literature reference: ECHA dossier; Reproductive toxicity: Method:: other guideline: US EPA Health Effects</p> <p>Testing Guidelines 40 CFR Part 798.2450 ; Species: Rat ;Exposure duration: 94 d. Result: NOAEL = 1500 ppm ; Reference: ECHA Dossier</p>

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	Specific target organ toxicity at single exposure	<p>Based on available data, the classification criteria are not met. Ethyl Acetate:</p> <p>In vitro mutagenicity: Method: OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test); Result Negative. Literature reference: ECHA dossier; No evidence of carcinogenicity in humans available.</p>

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	Specific target organ toxicity in case of repeated exposure	<p>Based on available data, the classification criteria are not met. Ethyl Acetate: In vitro mutagenicity: Method: OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test); Result Negative. Literature reference: ECHA dossier; No evidence of carcinogenicity in humans available. Literature reference: ECHA dossier; Reproductive toxicity: Method: other guideline: US EPA Health Effects Testing Guidelines 40 CFR Part 798.2450 ; Species: Rat ;Exposure duration: 94 d. Result: NOAEL = 1500 ppm ; Reference: ECHA Dossier Hydrocarbons, C9-C11, n-alkanes, iso-alkanes, cyclic compounds, aromatics (< 2%): In vitro mutagenicity: method: OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test) ; result: negative. Literature reference: ECHA Dossier; Carcinogenicity: Method: (dermal.) OECD Guideline 451 (Carcinogenicity Studies); Species: Mouse; Test duration: 2 years; Result: negative. Literature reference: ECHA Dossier; Reproductive Toxicity: Method: OECD Guideline 416 (Two-Generation Reproduction Toxicity Study);</p>

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		<p>Species: Rat; Result: NOAEL >= 20000 mg/kg; Reference: ECHA dossier. Developmental toxicity /Teratogenicity: Method: OECD Guideline 414 (Prenatal Developmental Toxicity Study); Species: Rat Result: NOAEL = 239000 mg/kg; Reference: ECHA Dossier 2-Propanol; Isopropyl alcohol; Isopropanol (CAS No.: 67-63-0): OECD Guideline 471 (Bacterial Reverse Mutation Assay) = negative, AllgK267153: ECHA Dossier; OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) = negative, Reference: ECHA dossier; None. No evidence of carcinogenicity in humans, reference: ECHA dossier; Reproductive toxicity: Method: OECD Guideline 415 (One-Generation Reproduction Toxicity Study); Species: rat ; Result: NOAEL = 853 mg/kg; Reference: ECHA dossier; Developmental toxicity / teratogenicity: Method: (oral.) OECD Guideline 414 (Prenatal Developmental Toxicity Study) ; Species: rabbit ; Result: NOAEL = 480 mg/kg; Reference: ECHA Dossier</p>
<p>Aspiration hazard</p>		<p>Based on available data, the classification criteria are not met. Ethyl Acetate: In vitro mutagenicity: Method: OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test); Result Negative. Literature reference: ECHA dossier; No evidence of carcinogenicity in humans available. Literature reference: ECHA dossier; Reproductive toxicity: Method:: other guideline: US EPA Health Effects Testing Guidelines 40 CFR Part 798.2450 ; Species: Rat ;Exposure duration: 94 d. Result: NOAEL = 1500 ppm ; Reference: ECHA Dossier Hydrocarbons, C9-C11, n-alkanes, iso-alkanes, cyclic compounds, aromatics (< 2%): In vitro mutagenicity: method: OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test) ; result: negative. Literature reference: ECHA Dossier; Carcinogenicity: Method: (dermal.) OECD Guideline 451 (Carcinogenicity Studies); Species: Mouse; Test duration: 2 years; Result: negative. Literature reference: ECHA Dossier; Reproductive Toxicity: Method: OECD Guideline 416 (Two-Generation Reproduction Toxicity Study); Species: Rat; Result: NOAEL >= 20000 mg/kg; Reference: ECHA dossier. Developmental toxicity /Teratogenicity: Method: OECD Guideline 414 (Prenatal Developmental Toxicity Study); Species: Rat Result: NOAEL = 239000 mg/kg; Reference: ECHA Dossier 2-Propanol; Isopropyl alcohol; Isopropanol (CAS No.: 67-63-0): OECD Guideline 471 (Bacterial Reverse Mutation Assay) = negative, AllgK267153: ECHA Dossier; OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) = negative, Reference: ECHA dossier; None. No evidence of carcinogenicity in humans, reference: ECHA dossier; Reproductive toxicity: Method: OECD Guideline 415 (One-Generation Reproduction Toxicity Study); Species: rat ; Result:</p>

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11.2	Information on other hazards	No data available.
11.2.1	Endocrine disrupting properties	No data available.
11.2.2	Other information	No data available.

SECTION 12. Environmental information

12.1	Toxicity																																																																																												
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		64742-48-9	Hydrocarbons, C9-C111, n-alkane, iso-alkane, cyclic compounds, aromatics (< 2 %)													
			OECD 301F/ ISO 9408/ EEC 92/69/V, C.4-D	80%	28	ECHA Dossier										
			Readily biodegradable (according to OECD criteria).													
		67-63-0	propan-2-ol; isopropyl alcohol; isopropanol													
			EU Method C.5/ EU Method C.6	53%	5	ECHA Dossier										
			Easily biodegradable (concerning to the criteria of the OECD)													
12.3	Bioaccumulative potential	<table border="1"> <thead> <tr> <th>CAS No</th> <th>Chemical name</th> <th>Log Pow</th> </tr> </thead> <tbody> <tr> <td>141-78-6</td> <td>ethyl acetate</td> <td>0,73</td> </tr> <tr> <td>67-63-0</td> <td>propan-2-ol; isopropyl alcohol; isopropanol</td> <td>0,05</td> </tr> </tbody> </table>						CAS No	Chemical name	Log Pow	141-78-6	ethyl acetate	0,73	67-63-0	propan-2-ol; isopropyl alcohol; isopropanol	0,05
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12.4	Mobility in soil	No data available.														
12.5	Results of the PBT and vPvB assessment	The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, Annex XIII.														
12.6	Endocrine disrupting properties	No data available.														
12.7	Other adverse effects	Do not allow to enter drains or water courses.														

SECTION 13: Disposal instructions

13.1	Waste treatment process	
	General information	<p>Recommendation</p> <p>Dispose of in accordance with official regulations. For waste disposal, contact the responsible authorized disposal company. Non-contaminated and empty packaging can be recycled. recycling. The assignment of waste code numbers/waste designations must be carried out in accordance with EAKV industry- and process-specific.</p> <p>Proposal list for waste codes/waste designations according to AVV: Waste code Product 200113 WASTES FROM FARMING (HOUSEHOLD WASTES AND SIMILAR COMMERCIAL AND INDUSTRIAL WASTE AND WASTE FROM FACILITIES), INCLUDING SEPARATELY COLLECTED FRACTIONS; Separately collected fractions (except 15 01); Solvents; Hazardous waste code Product residues 200113 WASTES (HOUSEHOLD WASTES AND SIMILAR COMMERCIAL AND INDUSTRIAL WASTES AND WASTES FROM FACILITIES) INDUSTRIAL WASTE AND WASTE FROM FACILITIES), INCLUDING SEPARATELY COLLECTED FRACTIONS; Separately collected fractions (except 15 01); Solvents; hazardous waste code uncleaned packaging 150110 PACKAGING WASTE, SUPPLIES, WIPING CLOTHES, FILTER MATERIALS, AND PROTECTIVE CLOTHING (A.N.G.); packaging (including separately collected municipal packaging waste); packaging that contains residues of hazardous substances or is contaminated by hazardous substances; hazardous waste.</p>
	Disposal methods	Contaminated packaging must be treated in the same way as the substance.

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SECTION 14: Transport information

14.1 ADR																									
	<table border="1"><tr><td>UN number</td><td>UN 1993</td></tr><tr><td>Proper shipping name UN Shipping Name:</td><td>FLAMMABLE LIQUID, N.O.S. (Ethyl acetate, Isopropyl alcohol.)</td></tr><tr><td>Transport hazard classes:</td><td>3</td></tr><tr><td>Packing group</td><td>II</td></tr><tr><td>Hazard label:</td><td>3 </td></tr><tr><td>Classification Code:</td><td>F1</td></tr><tr><td>Special Provisions:</td><td>274 601 640D</td></tr><tr><td>Limited Quantity (LQ):</td><td>1 L</td></tr><tr><td>Excepted quantity:</td><td>E2</td></tr><tr><td>Transport category:</td><td>2</td></tr><tr><td>Hazard number:</td><td>33</td></tr><tr><td>Tunnel Restriction Code:</td><td>D/E</td></tr></table>	UN number	UN 1993	Proper shipping name UN Shipping Name:	FLAMMABLE LIQUID, N.O.S. (Ethyl acetate, Isopropyl alcohol.)	Transport hazard classes:	3	Packing group	II	Hazard label:	3 	Classification Code:	F1	Special Provisions:	274 601 640D	Limited Quantity (LQ):	1 L	Excepted quantity:	E2	Transport category:	2	Hazard number:	33	Tunnel Restriction Code:	D/E
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Classification Code:	F1																								
Special Provisions:	274 601 640D																								
Limited Quantity (LQ):	1 L																								
Excepted quantity:	E2																								
Transport category:	2																								
Hazard number:	33																								
Tunnel Restriction Code:	D/E																								
14.4 IMDG																									
	<table border="1"><tr><td>UN number</td><td>UN 1993</td></tr><tr><td>Proper shipping name UN Shipping Name:</td><td>FLAMMABLE LIQUID, N.O.S. (Ethyl acetate, Isopropyl alcohol.)</td></tr></table>	UN number	UN 1993	Proper shipping name UN Shipping Name:	FLAMMABLE LIQUID, N.O.S. (Ethyl acetate, Isopropyl alcohol.)																				
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		<table border="1"> <tr> <td>Transport hazard classes:</td> <td>3</td> </tr> <tr> <td>Packing group</td> <td>II</td> </tr> <tr> <td>Hazard label:</td> <td>3 </td> </tr> <tr> <td>Marine pollutant:</td> <td>NO</td> </tr> <tr> <td>Special provisions:</td> <td>274</td> </tr> <tr> <td>Limited Quantity (LQ):</td> <td>1 L</td> </tr> <tr> <td>Excepted quantity:</td> <td>E2</td> </tr> <tr> <td>EmS:</td> <td>F-E, S-D</td> </tr> </table>	Transport hazard classes:	3	Packing group	II	Hazard label:	3 	Marine pollutant:	NO	Special provisions:	274	Limited Quantity (LQ):	1 L	Excepted quantity:	E2	EmS:	F-E, S-D								
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14.6	Special precautions for the user:	HARMFUL TO THE ENVIRONMENT: no See section 8..																								
14.7	Carriage in bulk in accordance with Annex II of the MARPOL Convention and the IBC Code:	not relevant.																								

SECTION 15: Legislation

15.1	Safety, health and environmental regulations/specific legislation for the substance or mixture:	
	EU regulations	
	Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex I, Controlled substances:	none
	Regulation (EU) 2019/1021 on persistent organic pollutants (new edition), as amended:	none
	Regulation (EC) No 649/2012 on the export and import of dangerous chemicals:	none
	Regulation (EC) No 1907/2006, REACH Annex XIV List of substances subject to authorisation, as amended:	none
	EU. REACH Candidate List of Substances of Very High Concern (SVHC) for authorisation:	none
	Regulation (EC) No 1907/2006 Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles :	The mixture is classified as dangerous according to

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		Regulation (EC) No 1272/2008 [CLP].
		REACH 1907/2006 Annex XVII, No. (mixture): 3, 40
	Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work...:	none
	Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:	none
	Directive 2012/18/EU (Seveso III) on the control of major-accident hazards involving dangerous substances:	
	REGULATION (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register, ANNEX II: Pollutants	none
	Directive 98/24/EU on the protection of workers from the risks related to chemical agents at work:	none
	National regulations	
	Water hazard class	1 - slightly hazardous to water
	Reference to Technical Rules for Hazardous Substances (TRGS)	Observe employment restrictions for young people (§ 22 JArbSchG). 5.2.5: Organic substances, indicated as total carbon at m >= 0.50 kg/h: Conc. 50 mg/m ³
	VOC Directive (1999/13/EC) and the Decopaint Directive (2004/42/EC)	none
	Other regulations	EU regulations Restrictions on use (REACH, Annex XVII): Entry 3: Ethyl acetate Ethyl acetate
15.2	Chemical safety assessment	2-propanol; isopropyl alcohol; isopropanol

SECTION 16: Other information

16.1	Information on the revision	Not relevant.
	Important literature references and data sources:	ADR: Accord européen sur le transport des marchandises dangereuses par Route

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	<p>AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen</p> <p>CAS Chemical Abstracts Service</p> <p>DNEL: Derived No Effect Level</p> <p>IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)</p> <p>ICAO: International Civil Aviation Organization</p> <p>ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)</p> <p>GHS: Globally Harmonized System of Classification and Labelling of Chemicals</p> <p>GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)</p> <p>LOAEL: Lowest observed adverse effect level</p> <p>LOAEC: Lowest observed adverse effect concentration</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>NOAEL: No observed adverse effect level NOAEC: No observed adverse effect level</p> <p>NTP: National Toxicology Program</p> <p>N/A: not applicable</p> <p>OSHA: Occupational Safety and Health Administration</p> <p>PNEC: predicted no effect concentration</p> <p>PBT: Persistent bioaccumulative toxic</p>
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	<p>RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)</p> <p>SARA: Superfund Amendments and Reauthorization Act</p> <p>SVHC: substance of very high concern</p> <p>TRGS Technische Regeln fuerGefahrstoffe</p> <p>TSCA: Toxic Substances Control Act</p> <p>VOC: Volatile Organic Compounds</p> <p>VwVwS: Verwaltungsvorschrift wassergefaehrdender Stoffe</p> <p>WGK: Wassergefaehrdungsklasse</p> <p>Einstufung von Gemischen und verwendete Wortlaut der H- und EUH-Sätze (Nummer und Volltext) H225 Flüssigkeit und Dampf leicht entzündbar.</p> <p>H226 Flüssigkeit und Dampf entzündbar.</p> <p>H304 Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein .</p> <p>H319 Verursacht schwere Augenreizung.</p> <p>H336 Kann Schläfrigkeit und Benommenheit verursachen.</p> <p>EUH066 Wiederholter Kontakt kann zu spröder oder rissiger Haut führen. ngsverfahren.</p> <p>Umweltgefahren: Berechnungsverfahren.</p> <p>Physikalische Gefahren: Auf Basis von Prüfdaten und / oder berechnet und / oder geschätzt.</p> <p>Die Angaben in diesem Sicherheitsdatenblatt entsprechen nach bestem Wissen unseren Erkenntnissen bei</p> <p>Drucklegung. Die Informationen sollen Ihnen Anhaltspunkte für den sicheren Umgang mit dem in diesem</p> <p>Sicherheitsdatenblatt genannten Produkt bei Lagerung, Verarbeitung, Transport und Entsorgung geben. Die</p>
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	<p>Angaben sind nicht übertragbar auf andere Produkte. Soweit das Produkt mit anderen Materialien vermengt, vermischt oder verarbeitet wird, oder einer Bearbeitung unterzogen wird, können die Angaben in diesem Sicherheitsdatenblatt, soweit sich hieraus nicht ausdrücklich etwas anderes ergibt, nicht auf das so gefertigte neue Material übertragen werden.</p> <p>Weitere Angaben Einstufung gemäß Verordnung (EG) Nr. 1272/2008 [CLP] - Einstufungsverfahren:</p> <p>Gesundheitsgefahren: Berechnungsverfahren.</p> <p>Umweltgefahren: Berechnungsverfahren.</p> <p>Physikalische Gefahren: Auf Basis von Prüfdaten und / oder berechnet und / oder geschätzt. Die Angaben in diesem Sicherheitsdatenblatt entsprechen nach bestem Wissen unseren Erkenntnissen bei Drucklegung. Die Informationen sollen Ihnen Anhaltspunkte für den sicheren Umgang mit dem in diesem Sicherheitsdatenblatt genannten Produkt bei Lagerung, Verarbeitung, Transport und Entsorgung geben. Die Angaben sind nicht übertragbar auf andere Produkte. Soweit das Produkt mit anderen Materialien vermengt, vermischt oder verarbeitet wird, oder einer Bearbeitung unterzogen wird, können die Angaben in diesem Sicherheitsdatenblatt, soweit sich hieraus nicht ausdrücklich etwas anderes ergibt, nicht auf das so gefertigte neue Material übertragen werden.</p>
Training information:	There are no data available.
Disclaimer:	<p>More information</p> <p>To the best of our knowledge, the information in this safety data sheet corresponds to our knowledge at the time of revision. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transportation and disposal. The information is not transferable to other products. Insofar as the product named in this safety data sheet is mixed, blended or processed with other materials, or is subjected to processing, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.</p>

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Regofix
Article no.: No. 93805

Revised on: 15.05.2023
Version: 1.0 Replaced version:



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

1.1	Product identifier	Regofix Article no.: 93805
1.2	Relevant identified uses of the substance or mixture and uses which are not recommended	
1.2.1	Relevant uses medical device:	Regofix
1.2.2	Uses that are not recommended:	None known
1.3	Details of the supplier providing the safety data sheet	Dr. Hinz Dental Vertriebsgesellschaft mbH & Co. KG Friedrich der Große 64 44628 Herne GERMANY Phone: + 49 (0) 23 23 / 59 34 20 Fax : + 49 (0) 23 23 / 59 34 29 E-Mail: qm@dhug.de
1.4	Emergency number	Contact: Dr. P. Hinz Phone: + 49 17 51 83 41 34

SECTION 2: Possible dangers

2.1	Classification of the substance or mixture The product has not been classified as dangerous according to the legislation in force	
2.1.1	Classification according to (EC) Regulation 1272/2008 as amended. Not classified	
2.2	Labelling elements Additional information:	Not applicable No data available
2.3	Other dangers	There are no data available

SECTION 3: Composition / Information on ingredients

3.1	Chemical characterisation	Addition-curing two-component silicone
3.1.1	Dangerous ingredients	The wording of the listed hazard statements can be found in section 16.

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Section 4: First aid measures

4.1	Description of the first aid measures	
	General notes	No special measures required.
	Inhalation:	Fresh air supply, consult doctor in case of complaints.
	Eye contact:	Rinse opened eye for several minutes under running water and consult a doctor.
	Skin contact:	In general, the product is not irritating to the skin.
	Ingestion:	Do not induce vomiting. Seek medical attention immediately.
4.2	Most important symptoms and effects, both acute and delayed:	No further relevant information available.
4.3	Indications for immediate medical help or special treatment	
	Dangers:	No further relevant information available.
	Treatment:	No further relevant information available.

SECTION 5: Fire-fighting measures

5.1	General fire hazards	Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.
	Extinguishing agent	
	Suitable extinguishing media	CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol-resistant foam.
	Unsuitable extinguishing media:	Water in full jet
5.2	Special hazards arising from the substance or mixture:	No further relevant information available.
5.3	Advice for firefighters	No special measures required
	Special protective equipment for fire fighting:	No special measures required

SECTION 6: Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures:	Avoid contact with eyes.
6.2	Environmental protection measures:	Do not allow to enter drains/surface waters/groundwater.

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6.3	Methods and material for retention and cleaning:	Absorb with liquid-binding material (sand, diatomaceous earth, acid binders, universal binders, sawdust)
6.4	Reference to other sections:	No hazardous substances are released. For information on safe handling, see section 7. For information on personal protective equipment see section 8. For disposal information, see Section 13.

Section 7: Handling and storage:

7.1	Protective measures for safe handling:	Do not eat, drink or smoke while working.
	Notes on fire and explosion protection:	Not required.
7.2	Conditions for safe storage taking into account incompatibilities:	Keep container tightly closed.
	Storage stability:	None.
	Storage class:	Storage class (TRGS 510): 10
7.3	Specific end uses:	There are no data available.

SECTION 8: Exposure controls/personal protective equipment

8.1	Parameters to be monitored Occupational exposure limit values	The product does not contain any relevant quantities of substances with workplace-related limit values to be limit values to be monitored.
	Biological limit values	No further information, see section 7.
8.2	Exposure controls Suitable engineering controls:	The product does not contain any relevant quantities of substances with workplace-related limit values to be limit values to be monitored. - Additional information: The lists valid at the time of preparation served as a basis.
	Individual protective measures, for example personal protective equipment	
	General information:	The usual precautions when handling chemicals must be observed.
	Eye/face protection:	Not required.
	Skin protection Hand protection:	Not required.
Other:	Not required.	

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Respiratory protection:	Not required.
Hygiene measures:	The usual precautions when handling chemicals must be observed.
Limitation and monitoring of environmental exposure:	Eye protection: Safety goggles recommended during decanting. - Body protection: Protective work clothing

SECTION 9: Physical and chemical properties

9.1	Information on the basic physical and chemical properties																																						
	<table border="1"><thead><tr><th>Parameter</th><th>Value</th></tr></thead><tbody><tr><td>State of aggregation</td><td>Viscose</td></tr><tr><td>Colour</td><td>Bluish transparent</td></tr><tr><td>Smell</td><td>Characteristic</td></tr><tr><td>Melting point/freezing point</td><td>Not determined.</td></tr><tr><td>Boiling point or initial boiling point and boiling range</td><td>> 300 °C</td></tr><tr><td>Flammability</td><td>There are no data available.</td></tr><tr><td>Lower explosion limit upper explosion limit</td><td>There are no data available. Es liegen keine Daten vor.</td></tr><tr><td>Flash point</td><td>> 130 °C</td></tr><tr><td>Ignition temperature</td><td>400°C</td></tr><tr><td>Decomposition temperature</td><td>There are no data available.</td></tr><tr><td>pH value</td><td>There are no data available.</td></tr><tr><td>Kinematic viscosity</td><td>There are no data available.</td></tr><tr><td>Solubility</td><td>Not miscible or only slightly miscible.</td></tr><tr><td>Partition coefficient n-octanol/water (log value)</td><td>There are no data available.</td></tr><tr><td>Vapour pressure</td><td>100 hPa</td></tr><tr><td>Density and/or specific gravity</td><td>1,3 g/cm³</td></tr><tr><td>Relative vapour density</td><td>There are no data available.</td></tr><tr><td>Particle properties</td><td>There are no data available.</td></tr></tbody></table>	Parameter	Value	State of aggregation	Viscose	Colour	Bluish transparent	Smell	Characteristic	Melting point/freezing point	Not determined.	Boiling point or initial boiling point and boiling range	> 300 °C	Flammability	There are no data available.	Lower explosion limit upper explosion limit	There are no data available. Es liegen keine Daten vor.	Flash point	> 130 °C	Ignition temperature	400°C	Decomposition temperature	There are no data available.	pH value	There are no data available.	Kinematic viscosity	There are no data available.	Solubility	Not miscible or only slightly miscible.	Partition coefficient n-octanol/water (log value)	There are no data available.	Vapour pressure	100 hPa	Density and/or specific gravity	1,3 g/cm ³	Relative vapour density	There are no data available.	Particle properties	There are no data available.
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Particle properties	There are no data available.																																						
9.2.	Other information There are no data available.																																						

SECTION 10: Stability and reactivity

10.1	Reactivity	No hazardous reactions if the regulations/instructions for storage and handling are observed.
10.2	Chemical stability	The product is stable if the regulations/instructions for storage and handling are observed.
10.3	Possibility of hazardous reactions	No dangerous reactions known.

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10.4	Conditions to avoid	No further relevant information available.
10.5	Incompatible materials	No further relevant information available.
10.6	Decomposition products	No hazardous decomposition products known

SECTION 11: Toxicological data

11.1	Information on hazard classes within the meaning of Regulation (EC) No 1272/2008	
	acute toxicity	Based on available data, the classification criteria are not met.
	Corrosive/irritant effect on the skin	Based on available data, the classification criteria are not met.
	Serious eye damage/irritation	Based on available data, the classification criteria are not met
	Sensitisation of the respiratory tract/skin	Based on available data, the classification criteria are not met
	Germ cell mutagenicity	Based on available data, the classification criteria are not met
	Carcinogenicity	Based on available data, the classification criteria are not met
	Reproductive toxicity	Based on available data, the classification criteria are not met
	Specific target organ toxicity at single exposure	Based on available data, the classification criteria are not met
	Specific target organ toxicity in case of repeated exposure	Based on available data, the classification criteria are not met
	Aspiration hazard	Based on available data, the classification criteria are not met
11.2	Information on other hazards	Based on available data, the classification criteria are not met
11.2.1	Endocrine disrupting properties	Based on available data, the classification criteria are not met
11.2.2	Other information	Based on available data, the classification criteria are not met

SECTION 12. Environmental information

12.1	Toxicity	No further relevant information available.
12.2	Persistence and degradability	No further relevant information available.
12.3	Bioaccumulative potential	No further relevant information available.
12.4	Mobility in soil	No further relevant information available.
12.5	Results of the PBT and vPvB assessment	No further relevant information available.
12.6	Endocrine disrupting properties	No further relevant information available.
12.7	Other adverse effects	No further relevant information available.

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SECTION 13: Disposal instructions

13.1	Waste treatment process	
	General information	Dispose of in accordance with official regulations.
	Disposal methods	Dispose of in accordance with official regulations.

SECTION 14: Transport information

14.1	ADR	Not dangerous goods
14.2	ADN	Not dangerous goods
14.3	RID	Not dangerous goods
14.4	IMDG	Not dangerous goods
14.5	IATA	Not dangerous goods
14.6	Special precautions for the user:	Not dangerous goods
14.7	Carriage in bulk in accordance with Annex II of the MARPOL Convention and the IBC Code:	Not dangerous goods

SECTION 15: Legislation

15.1	Safety, health and environmental regulations/specific legislation for the substance or mixture:	
	EU regulations	
	Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex I, Controlled substances:	none
	Regulation (EU) 2019/1021 on persistent organic pollutants (new edition), as amended:	none
	Regulation (EC) No 649/2012 on the export and import of dangerous chemicals:	none
	Regulation (EC) No 1907/2006, REACH Annex XIV List of substances subject to authorisation, as amended:	none
	EU. REACH Candidate List of Substances of Very High Concern (SVHC) for authorisation:	none
	Regulation (EC) No 1907/2006 Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles : Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work...:	none

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	Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:	none
	Directive 2012/18/EU (Seveso III) on the control of major-accident hazards involving dangerous substances:	none
	REGULATION (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register, ANNEX II: Pollutants	none
	Directive 98/24/EU on the protection of workers from the risks related to chemical agents at work:	none
	National regulations	
	Water hazard class	Water hazard class 1 (self-classification): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. sewerage system.
	Reference to Technical Rules for Hazardous Substances (TRGS)	none
	VOC Directive (1999/13/EC) and the Decopaint Directive (2004/42/EC)	none
	Other regulations	none
15.2	Chemical safety assessment	A chemical safety assessment has not been carried out

SECTION 16: Other information

16.1	Information on the revision	Not relevant.
	Important literature references and data sources:	There are no data available.
	Training information:	There are no data available.
	Disclaimer:	More information To the best of our knowledge, the information in this safety data sheet corresponds to our knowledge at the time of revision. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transportation and disposal. The information is not transferable to other products. Insofar as the product named in this safety data sheet is mixed, blended or processed with other materials, or is subjected to processing, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.

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

1.1	Product identifier	Bruxi+ starter set Article no.: 93805_B
1.2	Relevant identified uses of the substance or mixture and uses which are not recommended	
1.2.1	Relevant uses medical device:	Silikon Elastomer (B)
1.2.2	Uses that are not recommended:	None known
1.3	Details of the supplier providing the safety data sheet	Dr. Hinz Dental Vertriebsgesellschaft mbH & Co. KG Friedrich der Große 64 44628 Herne GERMANY Phone: + 49 (0) 23 23 / 59 34 20 Fax : + 49 (0) 23 23 / 59 34 29 E-Mail: qm@dhug.de
1.4	Emergency number	Contact: Dr. P. Hinz Phone: + 49 17 51 83 41 34

SECTION 2: Possible dangers

2.1	Classification of the substance or mixture	The product has not been classified as hazardous according to the legislation in force.
2.1.1	Classification according to (EC) Regulation 1272/2008 as amended.	Not classified
2.2	Labelling elements Additional information:	Not applicable No data available
2.3	Other dangers	There are no data available.

SECTION 3: Composition / Information on ingredients

3.1	Chemical characterisation	Vinyl group-containing polydimethylsiloxane with fillers, crosslinker and inhibitor.
3.1.1	Dangerous ingredients	No hazardous ingredients.

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Section 4: First aid measures

4.1	Description of the first aid measures	
	General notes	No action should be taken that involves personal risk or has not been adequately trained.
	Inhalation:	Remove to fresh air. Seek medical attention if symptoms occur.
	Eye contact:	Immediately flush eye with water. Seek medical attention if symptoms occur.
	Skin contact:	Wash the area with soap and water. Remove contaminated, soaked clothing. Seek medical attention if symptoms occur.
	Ingestion:	Do NOT induce vomiting if swallowed. Administer a glass of water. Seek medical attention.
4.2	Most important symptoms and effects, both acute and delayed:	not known
4.3	Indications for immediate medical help or special treatment	
	Dangers:	This product is not expected to be harmful under normal use and proper personal hygiene.
	Treatment:	Do NOT induce vomiting if swallowed. Administer a glass of water.

SECTION 5: Fire-fighting measures

5.1	General fire hazards	Do not allow runoff of fire extinguishing materials, even in diluted form, to reach water bodies, sewage system or drinking water reservoirs. In case of insufficient ventilation, put on breathing apparatus. Remove containers from the fire area as far as this is possible without danger.
	Extinguishing agent Suitable extinguishing media	Use water mist, alcohol-resistant foam, dry chemical or carbon dioxide (CO ₂) to extinguish flames.
	Unsuitable extinguishing media:	Avoid direct water jets; this will scatter and spread the fire.
5.2	Special hazards arising from the substance or mixture:	Cool containers exposed to fire with a water spray. In case of fire, carbon monoxide and carbon dioxide may be formed. Reacts with bases to liberate flammable gases.
5.3	Advice for firefighters Advice for firefighters:	Keep away from sources of ignition - Do not smoke.
	Special protective equipment for fire fighting:	Fire personnel must wear standard protective equipment, including flame retardant coats, helmets with face shields, gloves, rubber boots, and self-contained breathing apparatus in confined spaces.

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SECTION 6: Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures:	Remove all sources of ignition. Wear personal protective equipment.
6.2	Environmental protection measures:	Do not allow runoff to enter drains, waterways or soil.
6.3	Methods and material for retention and cleaning:	Absorb with vermiculite, dry sand or soil and place in containers. Thoroughly clean surfaces to remove residual contamination. Caution: Contaminated surfaces may be slippery.
6.4	Reference to other sections:	Do not allow runoff to reach drains, sewers or bodies of water. Caution: Contaminated surfaces may be slippery.

Section 7: Handling and storage:

7.1	Protective measures for safe handling:	Pack this product in unbreakable containers (no glass containers!) to avoid contact with the substances mentioned in chapter 10. Keep away from food, beverages and animal feed. Use only in well-ventilated areas. Do not eat, drink or smoke while working.
	Notes on fire and explosion protection:	Keep container tightly closed. Store in the original container. Keep away from heat and open flame.
7.2	Conditions for safe storage taking into account incompatibilities:	Store the product in the original tightly closed container in a dry and cool place. Keep away from water, acids, bases, amines, alcohols.
	Storage stability:	The material is stable under normal conditions.
	Storage class:	(TRGS 510): 12
7.3	Specific end uses:	There are no data available.

SECTION 8: Exposure controls/personal protective equipment

8.1	Parameters to be monitored Occupational exposure limit values	Occupational exposure limits do not apply to any of the ingredients.
	Biological limit values	None(s).
8.2	Exposure controls Suitable engineering controls:	No special requirements under normal conditions of use and with adequate ventilation. Eye wash bottle with pure water.
	Individual protective measures, for example personal protective equipment	
	General information:	Eye wash bottle with pure water. Do not eat, drink or smoke when handling the product. Wash hands after handling. Avoid contact with skin and eyes.
	Eye/face protection:	Safety goggles with side protection according to EN 167

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Skin protection	Note: There is no risk of contact with chemicals. Use hand protection to avoid mechanical injuries.
Hand protection:	
Other:	Before handling this product, personal protective equipment should be selected based on the task to be performed and the risks involved, and approved by a specialist.
Respiratory protection:	Under ordinary conditions of use and with adequate ventilation, protective clothing is not normally required.
Hygiene measures:	Avoid contact with skin and eyes. Observe recognized industrial hygiene measures. Do not eat, drink or smoke while working. Wash hands after handling.
Limitation and monitoring of environmental exposure:	There are no data available.

SECTION 9: Physical and chemical properties

9.1	Information on the basic physical and chemical properties																																						
	<table border="1"><thead><tr><th>Parameter</th><th>Value</th></tr></thead><tbody><tr><td>State of aggregation</td><td>liquid/ paste</td></tr><tr><td>Colour</td><td>colorless</td></tr><tr><td>Smell</td><td>Weak</td></tr><tr><td>Melting point/freezing point</td><td>There are no data available.</td></tr><tr><td>Boiling point or initial boiling point and boiling range</td><td>> 300 °C</td></tr><tr><td>Flammability</td><td>here are no data available.</td></tr><tr><td>Lower explosion limit upper explosion limit</td><td>here are no data available.</td></tr><tr><td>Flash point</td><td>> 100 °C</td></tr><tr><td>Ignition temperature</td><td>Minimum ignition temperature: 435 °C</td></tr><tr><td>Decomposition temperature</td><td>The material is stable under normal conditions.</td></tr><tr><td>pH value</td><td>Not applicable</td></tr><tr><td>Kinematic viscosity</td><td>< 4.200 mm²/s (20 °C)</td></tr><tr><td>Solubility</td><td>ubility (other): Soluble in toluene</td></tr><tr><td>Partition coefficient n-octanol/water (log value)</td><td>here are no data available.</td></tr><tr><td>Vapour pressure</td><td>1< 5 hPa (20 °C) (EG A4) < 15 hPa (50 °C) (EG A4)</td></tr><tr><td>Density and/or specific gravity</td><td>1,13 g/cm³ (20 °C) (DIN 51757)</td></tr><tr><td>Relative vapour density</td><td>here are no data available.</td></tr><tr><td>Particle properties</td><td>here are no data available.</td></tr></tbody></table>	Parameter	Value	State of aggregation	liquid/ paste	Colour	colorless	Smell	Weak	Melting point/freezing point	There are no data available.	Boiling point or initial boiling point and boiling range	> 300 °C	Flammability	here are no data available.	Lower explosion limit upper explosion limit	here are no data available.	Flash point	> 100 °C	Ignition temperature	Minimum ignition temperature: 435 °C	Decomposition temperature	The material is stable under normal conditions.	pH value	Not applicable	Kinematic viscosity	< 4.200 mm ² /s (20 °C)	Solubility	ubility (other): Soluble in toluene	Partition coefficient n-octanol/water (log value)	here are no data available.	Vapour pressure	1< 5 hPa (20 °C) (EG A4) < 15 hPa (50 °C) (EG A4)	Density and/or specific gravity	1,13 g/cm ³ (20 °C) (DIN 51757)	Relative vapour density	here are no data available.	Particle properties	here are no data available.
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9.2.

Other information

Auto-ignition temperature:
No data available.

SECTION 10: Stability and reactivity

10.1	Reactivity	here are no data available.
10.2	Chemical stability	The material is stable under normal conditions.
10.3	Possibility of hazardous reactions	Dangerous polymerization does not take place.
10.4	Conditions to avoid	Product generates a flammable gas in contact with acids, bases or oxidizing substances. Protect from heat. Keep away from moisture.
10.5	Incompatible materials	Hydrogen evolution with acids, alkalis, alcohols, powdered metals or metal oxides.
10.6	Decomposition products	Carbon oxides Silicon oxides. Measurements at temperatures above 150 °C in the presence of air (oxygen) have shown that small amounts of formaldehyde are formed by oxidative degradation.

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SECTION 11: Toxicological data

11.1	Information on hazard classes within the meaning of Regulation (EC) No 1272/2008	
	acute toxicity	Our experience shows that our Silopren elastomer products can be handled without any health hazards if they are handled properly and in accordance with the usual working hygiene.
	Corrosive/irritant effect on the skin	ATEmix (estimated acute toxicity of the mixture): 115,384.62 mg/kg
	Serious eye damage/irritation	here are no data available.
	Sensitisation of the respiratory tract/skin	here are no data available.
	Germ cell mutagenicity	here are no data available.
	Carcinogenicity	here are no data available.
	Reproductive toxicity	here are no data available.
	Specific target organ toxicity at single exposure	here are no data available.
	Specific target organ toxicity in case of repeated exposure	here are no data available.
	Aspiration hazard	here are no data available.
11.2	Information on other hazards	here are no data available.
11.2.1	Endocrine disrupting properties	The substance/mixture does not contain any components that are subject to REACH Article 57(f) or the Delegated Regulation (EU) 2017/2100 of the Commission or Commission Delegated Regulation (EU) 2018/605. Commission in quantities of 0.1% or more have endocrine disrupting Properties..;
11.2.2	Other information	here are no data available.

SECTION 12. Environmental information

12.1	Toxicity	"There areFish Product: No data available. Aquatic invertebrates Product: No data available. Chronic toxicity Fish Product: No data available. Aquatic invertebrates
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		Product: No data available. Toxicity to aquatic plants Product: No data available. no data available."
12.2	Persistence and degradability	here are no data available.
12.3	Bioaccumulative potential	here are no data available.
12.4	Mobility in soil	here are no data available.
12.5	Results of the PBT and vPvB assessment	here are no data available.
12.6	Endocrine disrupting properties	The substance/mixture does not contain any components that are subject to REACH Article 57(f) or the Delegated Regulation (EU) 2017/2100 of the Commission or Commission Delegated Regulation (EU) 2018/605. Commission in quantities of 0.1% or more have endocrine disrupting Properties.;
12.7	Other adverse effects	Ecotoxicological data on the product are not available.

SECTION 13: Disposal instructions

13.1	Waste treatment process	
	General information	Waste generation should be avoided or minimized whenever possible. See Section 8 for information regarding appropriate personal protective equipment. Do not allow to enter drains, waterways or soil.
	Disposal methods	Can be incinerated as long as it complies with local regulations.

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SECTION 14: Transport information

14.1	ADR	Not dangerous goods
14.2	ADN	Not dangerous goods
14.3	RID	Not dangerous goods
14.4	IMDG	Keep separate from food and beverages. This product is not a dangerous good according to the currently valid national and international dangerous good regulations.
14.5	IATA	Not dangerous goods
14.6	Special precautions for the user:	Not dangerous goods
14.7	Carriage in bulk in accordance with Annex II of the MARPOL Convention and the IBC Code:	Not applicable

SECTION 15: Legislation

15.1	Safety, health and environmental regulations/specific legislation for the substance or mixture:	
	EU regulations	
	Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex I, Controlled substances:	none
	Regulation (EU) 2019/1021 on persistent organic pollutants (new edition), as amended:	none
	Regulation (EC) No 649/2012 on the export and import of dangerous chemicals:	none
	Regulation (EC) No 1907/2006, REACH Annex XIV List of substances subject to authorisation, as amended:	none
	EU. REACH Candidate List of Substances of Very High Concern (SVHC) for authorisation:	none
	Regulation (EC) No 1907/2006 Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles :	none
	Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work...:	none
	Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:	none
	Directive 2012/18/EU (Seveso III) on the control of major-accident hazards involving dangerous substances:	none
	REGULATION (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register, ANNEX II: Pollutants	none
	Directive 98/24/EU on the protection of workers from the risks related to chemical agents at work:	none
	National regulations	

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	Water hazard class	Ordinance on Installations for Handling Substances Hazardous to Water (AwSV). WGK 1: slightly hazardous to water. Classification according to AwSV, Annex 1 (5.2)
	Reference to Technical Rules for Hazardous Substances (TRGS)	Technical Instructions on Air Quality Control (TA-Luft): Octamethylcyclotetrasiloxane Number 5.2.5 Class II, Organic substances
	VOC Directive (1999/13/EC) and the Decopaint Directive (2004/42/EC)	none
	Other regulations	none
15.2	Chemical safety assessment	No chemical safety assessment has been carried out.

SECTION 16: Other information

16.1	Information on the revision	Not relevant.
	Important literature references and data sources:	There are no data available.
	Training information:	There are no data available.
	Disclaimer:	More information To the best of our knowledge, the information in this safety data sheet corresponds to our knowledge at the time of revision. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transportation and disposal. The information is not transferable to other products. Insofar as the product named in this safety data sheet is mixed, blended or processed with other materials, or is subjected to processing, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.