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

Silasto®-Glänzer Article no.: No. 97408

Revised on: 15.05.2023



	SECTION 1: Identification of the substance or mixture and of the company/undertaking		
1.1	Product identifier	Silasto®-Glänzer Article no.: 97408	
1.2	Relevant identified uses of the sul	bstance 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 hazard	ous 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	Chemical name: Tetraethylsilicate Concentration: 1 - <5% CAS No.: 78-10-4 EC no.: 201-083-8	

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REACH Registration No : 01-2119496195-28-0002
M-factor : No data available.
Notes #
Chemical Name:
Decamethylcyclopentasiloxane
Concentration: 0.1 - <1%
CAS No.: 541-02-6
EC no. : 208-764-9
REACH Registration No : 01-2119511367-43-0002
M-factor: No data available.
Indications: vPvB
IIIUICALIOIIS . VEVD
Chemical name:
Dodecamethylcyclohexasiloxane
Concentration: 0.1 - <1%
CAS No.: 540-97-6
EC no. : 208-762-8
REACH Registration No. : 01-2119517435-42-0001
M-factor: No data available.
Indications: vPvB
* All concentrations are expressed as percentages by weight if the
ingredient is not a gas. Gas concentrations are given as volume
percent.
Occupational exposure limits exist for this substance.
PBT: Persistent, bioaccumulative and toxic substance.
vPvB: Very persistent and very bioaccumulative substance.
Classification
Chemical name: Tetraethylsilicate
Classification: Flam. Liq.: 3: H226; Acute Tox.: 4: H332; Eye Irrit.: 2:
H319; STOT SE: 3: H335;
Remarks No data available.
Chemical name: Decamethylcyclopentasiloxane
Classification: No data available.
Remarks No data available.
Chemical name:Dodecamethylcyclohexasiloxane
Classification: No data available.
Remarks No data available.

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 occ
	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 h	elp or special treatment

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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 (CO2) 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.	

	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.

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	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:	Class 10: Flammable liquids	
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	Chemical name: Tetraethyl silicate - inhalable fraction. Type: MAK Exposure limits: 10 ppm 86 mg/m3 Source: Germany. DFG-MAK list (recommended occupational exposure limits). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG) (2014) Chemical name: Tetraethylsilicate Type: TWA Exposure limits: 5 ppm 44 mg/m3 Source: EU. Indicative exposure limit values in Directive 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EC (02 2017) Type: TWA exposure limit values: 5 ppm 44 mg/m3 Source:EU. Scientific Committee for Occupational Exposure Limits (SCOEL), European Commission, SCOEL (2014) Type: AGW exposure limits: 1.4 ppm 12 mg/m3 Source:Germany. TRGS 900, Occupational air exposure limits (03 2015).
	Biological limit values	None(s). DNEL values Critical Component: Tetraethylsilicate Type: Worker Exposure Route: Skin contact 12.1 mg/kg bw/day Inhalation 85 mg/m3 Skin contact: 12.1 mg/kg bw/day Inhalation: 85 mg/m3 Type: Consumer Exposure Route: Skin Contact 8.4 mg/kg bw/day Inhalation: 25 mg/m3 Skin Contact: 8.4 mg/kg bw/day Inhalation: 25 mg/m3 PNEC Values Critical Component: tetraethyl silicate Environmental Compartment: Water 0.192 mg/l Seawater 0.0192 mg/l Periodic Release 10 mg/l Sediment: 0.18 mg/kg

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		Remarks: Derived from PNEC (fresh water) using equilibrium partition coefficient method soil 0.05 mg/kg.
		Derived from PNEC (fresh water) by equilibrium partition coefficient method wastewater treatment plant 4000 mg/l
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 exa	mple 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 169
	Skin protection Hand protection:	Note: There is no risk of contact with chemicals. Use hand protection to avoid mechanical injuries.
	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		
	Parameter	Value	
	State of aggregation	liquid / liquid	
	Colour	colorless	
	Smell	Weak	
	Melting point/freezing point	There are no data available.	
	Boiling point or initial boiling point and boiling range	here are no data available.	
	Flammability	here are no data available.	
	Lower explosion limit upper explosion limit	here are no data available.	
	Flash point	200 °C	
	Ignition temperature	here are no data available.	
	Decomposition temperature	The material is stable under normal conditions.	
	pH value	here are no data available.	
	Kinematic viscosity	Viscosity, dynamic: 30,000 mPa-s (23 °C) Viscosity, kinematic: No data available.	

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	Solubility	here are no data available.
	Partition coefficient n-octanol/water (log value)	here are no data available.
	Vapour pressure	here are no data available.
	Density and/or specific gravity	1,05 g/cm3
	Relative vapour density	here are no data available.
	Particle properties	here are no data available.
9.2.	Other information here are 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 Ingestion Product: Not classified for acute toxicity based on available data. Specific substance(s): Tetraethyl silicate No data available. Decamethylcyclopentasiloxane No data available. Dodecamethylcyclohexasiloxane LD 50 (rat): 2,000 mg/kg Skin contact Product: Not classified for acute toxicity based on available data. Specific substance(s) Tetraethylsilicate No data available. Decamethylcyclopentasiloxane LD 50 (rabbit): > 2,000 mg/kg Dodecamethylcyclohexasiloxane LD 50 (rat): 2,000 mg/kg Inhalation Product: ATEmix (estimated acute toxicity of mixture)221.86 mg/l Vapor ATEmix (estimated acute toxicity of mixture)30.25 mg/l Dust, mist and fume Specific substance(s): tetraethyl silicate No data available. Decamethylcyclopentasiloxane: LC50 (rat, 4 h): 8.67 mg/l Dodecamethylcyclohexasiloxane: No data available. acute toxicity Repeated dose toxicity Product: No data available. Specific substance(s): Tetraethyl NOAEL (no observable adverse effect level) (rat(male and female), ingestion, 28 d): 10 - 50 mg/kg LOAEL (lowest dose with observable adverse effect) (mouse(male), inhalation, 28 d): 50 mg/kg Decamethylcyclopentasiloxane NOAEL (Dose with no observable adverse effect) (rat(male and female), ingestion, 90 d): 1,000 mg/kg NOAEL (dose with no observable adverse effect) (rat(male and female), skin contact, 28 d): 1,600 mg/kg NOAEC (rat(male and female), inhalation - vapor, 2 a): 160 ppm Dodecamethylcyclohexasiloxane NOAEL (dose with no observable adverse effect) (rat(male and female), ingestion): 1,000 mg/kg

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Corrosive/irritant effect on the skin	Product: No data available. Specific substance(s) Tetraethylsilicate OECD Test Guideline 404 (Rabbit): Non-irritant Decamethylcyclopentasiloxane OECD Test Guideline 404 (Rabbit, 72 h): Non-irritant Dodecamethylcyclohexasiloxane OECD Guideline 404 (Acute Dermal Irritation/Corrosion) (Rabbit, 72 h): No skin irritation.
Serious eye damage/irritation	Product: No data available. Specific substance(s): Tetraethyl silicate OECD- Test guideline 405 (Rabbit, 72 h): Non-irritant Decamethylcyclopentasiloxane OECD Test Guideline 405 (Rabbit, 72 h): Non-irritant Dodecamethylcyclohexasiloxane OECD Guideline 405 (Acute Eye Irritation/Corrosion) (Rabbit, 72 h): No eye irritation Non-irritant
Sensitisation of the respiratory tract/skin	Product: No data available. Specific substance(s): Tetraethyl silicate OECD- Test guideline 405 (Rabbit, 72 h): Non-irritant Decamethylcyclopentasiloxane OECD Test Guideline 405 (Rabbit, 72 h): Non-irritant Dodecamethylcyclohexasiloxane OECD Guideline 405 (Acute Eye Irritation/Corrosion) (Rabbit, 72 h): No eye irritation Non-irritant In vitro
Germ cell mutagenicity	Product: No data available. Specific substance(s): Tetraethylsilicate In Chinese hamster ovum (CHO) (OECD 476): negative Chromosomal aberration (OECD 473): negative Decamethylcyclopentasiloxane Ames test (OECD Guideline 471 (Genetic Toxicology: Salmonella typhimurium, Reverse Mutation Assay)): negative (non-mutagenic) Mammalian cytogenetic test (Mouse Lymphoma Test (OECD Guideline 476)): negative (not mutagenic) Chromosomal aberration (OECD 473): negative (not mutagenic) Dodecamethylcyclohexasiloxane Ames test (OECD Guideline 471 (Genetic Toxicology: Salmonella typhimurium, Reverse Mutation Assay)): negative

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		In vivo
		Product: No data available.
		Specific substance(s): Tetraethylsilicate
		No data available.
		Decamethylcyclopentasiloxane
		(OECD Guideline 474 (Genetic Toxicology: Micronucleus Test)) Inhalation (rat, male and female)negative (not mutagenic) Vapor
		Dodecamethylcyclohexasiloxane
		OECD Guideline 474 (Genetic Toxicology: Micronucleus Test) (OECD Guideline 474 (Genetic Toxicology: Micronucleus
	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	here are no data available.
11.2.2	Other information	here are no data available.

SECTION 12. Environmental information			
12.1	Toxicity	Fish	
		Product: No data available.	
		Specific substance(s): Tetraethyl silicate	
		LC50 (Brachydanio rerio, 96 h): > 245 mg/l (Tested according to 92/69/EEC.)	
		Decamethylcyclopentasiloxane	
		LC50 (Oncorhynchus mykiss, 96 h): > 0.0016 mg/l (OECD Guideline 204)	
		Dodecamethylcyclohexasiloxane:No data available.	

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	Aquatic invertebrates
	Product:No data available.
	Specific substance(s): Tetraethyl silicate
	EC50 (Daphnia magna, 48 h): > 75 mg/l (OECD Guideline 202)
	Decamethylcyclopentasiloxane
	EC50 (Daphnia magna, 48 h): > 0.0029 mg/l (OECD Test Guideline 202)
	Dodecamethylcyclohexasiloxane: No data available.
	Chronic toxicity
	Fish
	Product: No data available.
	Specific substance(s): Tetraethyl silicate No data available.
	Decamethylcyclopentasiloxane
	NOEC (Oncorhynchus mykiss, 90 d): >= 0.0014 mg/l (OECD Guideline 210)
	LOEC (Oncorhynchus mykiss, 90 d): > 0.0014 mg/l (OECD Guideline 210)
	Dodecamethylcyclohexasiloxane
	NOEC (Pimephales promelas, 49 d): 0.0044 mg/l
	Aquatic invertebrates
	Product: No data available.
	Specific substance(s): Tetraethylsilicate
	No data available.
	Decamethylcyclopentasiloxane
	NOEC (Daphnia magna, 21 d): >= 0.0015 mg/l (OECD Guideline 211)
	LOEC (Daphnia magna, 21 d): > 0.0015 mg/l

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		Dodecamethylcyclohexasiloxane
		NOEC (Daphnia magna, 21 d): 0.0046 mg/l
		EC50 (Sediment / Invertebrates, 28 d): > 420 mg/l
		LOEC (Sediment / Invertebrates, 28 d): >= 420 mg/l
		Toxicity to aquatic plants
		Product: No data available.
		Specific substance(s): Tetraethyl silicate
		EC50 (Algae (Pseudokirchneriella subcapitata), 72 h): > 100 mg/l (OECD Test Guideline 201).
		Decamethylcyclopentasiloxane
		EC50 (Algae (Pseudokirchneriella subcapitata), 96 h): > 0.0012 mg/l (OECD Test Guideline 201)
		NOEC : >= 0.0012 mg/l
		EC10 : > 0.0012 mg/l
		Dodecamethylcyclohexasiloxane
		EC50 (algae (Pseudokirchneriella subcapitata), 72 h): > 0.002 mg/l (OECD Test Guideline 201)
		NOEC (Algae (Pseudokirchneriella subcapitata), 72 h): >= 0.002 mg/l (OECD Test Guideline 201)
12.2	Persistence and degradability	Biodegradation
		Product: No data available.
		Specific substance(s): Tetraethylsilicate
		Activated sludge, municipal (adaptation not specified) (28 d, OECD Guideline 301 A (DOC Die-Away Test)): 98 % Readily biodegradable
		Decamethylcyclopentasiloxane
		Activated sludge (adaptation not stated) (28 d, OECD- Test Guideline 310): 0.14 % The product is not readily biodegradable.

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		Dodecamethylcyclohexasiloxane: No data available.	
		BOD/COD ratio	
		Product: No data available.	
		Specific substance(s): Tetraethylsilicate: No data available.	
		Decamethylcyclopentasiloxane: No data are available.	
		Dodecamethylcyclohexasiloxane: No data available.	
12.3	Bioaccumulative potential	Product: No data available.	
		Specific substance(s): Tetraethyl silicate	
		No data available.	
		Decamethylcyclopentasiloxane	
		Thick head minnow, Bioconcentration Factor (BCF): 7,060 (OECD Test Guideline 305)	
		Dodecamethylcyclohexasiloxane: No data available.	
12.4	Mobility in soil	here are no data available.	
12.5	Results of the PBT and vPvB assessment	vPvB: Very persistent and very bioaccumulative substance.	
		Tetraethyl silicate: No data available.	
		Decamethylcyclopentasiloxane	
		vPvB: Very persistent and very bioaccumulative substance.	
		Decamethylcyclotetrasiloxane (D5) meets the current criteria of Annex XIII of the EU REACH Regulation for vPvB and has been placed on the Candidate List of Substances of Very High Concern (SVHCs),However, according to our understanding of the state of the science, D5 does not behave in a comparable way to the known PBT/vPvB substances. According to the silicone industry's interpretation of the available data, the scientific evidence derived from field trials essentially does not indicate that D5 is non-biomagnifying in aquatic and terrestrial food chains. D5 in air decomposes by processes naturally occurring in the atmosphere. Residues of D5 in air that do not decompose by these means are not expected to be deposited from there in water, soil, or living organisms. Dodecamethylcyclohexasiloxane	
		vPvB: Very persistent and very bioaccumulative substance.	
		Dodecamethylcyclohexasiloxane (D6) meets the current criteria of Annex XIII of the EU REACH Regulation for vPvB and has been placed on the Candidate	

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		List of Substances of Very High Concern (SVHCs).,However, our understanding of the state of the science is that D6 does not behave comparably to known PBT/vPvB substances. According to the silicone industry's interpretation of the available data, the scientific evidence derived from field trials essentially does not indicate that D6 is non-biomagnifying in aquatic and terrestrial food chains. D6 in air decomposes by processes naturally occurring in the atmosphere. Residues of D5 in air that do not decompose in this manner are not expected to be deposited from there in water, soil, or living organisms.
12.6	Endocrine disrupting properties	here are no data available.
12.7	Other adverse effects	here are no data 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.		

	SECTION 14: Transport information		
14.1	ADR	Not dangerous goods	
14.2	ADN	Not dangerous goods	
14.3	RID	This product is not subject to prohibition for transportation by air under national or international dangerous goods regulations. Due to the possible formation of hydrogen under certain conditions, Momentive Performance Materials recommends transporting this product by modes other than air (IATA-C, IATA-P). Keep separate from food and beverages.	
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 applicable	

	SECTION 15: Legislation		
15.1	tance or mixture:		
	Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex I, Controlled substances:	none	

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amended:	
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:	Chemical name :Decamethylcyclopenta
	CAS No. 541-02-6
	Concentration :0 - <=0.
	Chemical name :Dodecamethylcyclohex
	CAS No. 540-97-6
	Concentration:0 - <=0.1
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	none
recently given birth or are breastfeeding:	none
recently given birth or are breastfeeding: Directive 2012/18/EU (Seveso III) on the control of major-accident hazards involving dangerous substances:	
Directive 2012/18/EU (Seveso III) on the control of major-accident hazards	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	
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 Directive 98/24/EU on the protection of workers from the risks related to chemical	none Chemical name:
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 Directive 98/24/EU on the protection of workers from the risks related to chemical	none Chemical name: Tetraethylsilicate

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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)	none
	VOC Directive (1999/13/EC) and the Decopaint Directive (2004/42/EC)	none
	Other regulations	Directive 96/82/EC (Seveso III) on the control of major-accident hazards involving dangerous substances:
		Chemical name: Tetraethylsilicate.
		CAS No. 78-10-4
1= 4		Concentration: 1.0 - 10%
15.2	Chemical safety assessment	No chemical safety assessment has been carried out.

SECTION 16: Other information		
1	Information on the revision	Not relevant.
	Important literature references and data sources:	No data available.wording of H-phrases in chapter 2 and 3
		H226
		Flammable liquid and vapor.
		H319
		Causes severe eye irritation.
		H332
		Harmful by inhalation.
		H335
		May cause respiratory irritation.
	Training information:	There are no data available.
	Disclaimer:	More information

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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 intende 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 otherwis

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	SECTION 1: Identification of the substance or mixture and of the company/undertaking		
1.1	Product identifier	Silasto®-Glänzer	
		Article no.: 97408_A	
1.2	Relevant identified uses of the sub	ostance or mixture and uses which are not recommended	
1.2.1	Relevant uses medical device:	Silikon Elastomer (A)	
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	Endocrine disrupting properties toxicity The substance/mixture does not contain any components that are classified as endocrine disruptors according to REACH Article 57(f) or the Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU). 2018/605 of the Commission in quantities of 0.1% or more endocrine disrupting properties. exhibit endocrine disrupting properties. Endocrine disrupting properties-ecotoxicity. The substance/mixture does not contain any components that are endocrine disruptors according to REACH Article 57(f) or the Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 of the Commission in quantities of 0.1% or more endocrine disrupting properties. exhibit.

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	SECTION 3: Composition / Information on ingredients		
3.1	Chemical characterisation	Vinyl group-containing polydimethylsiloxane with platinum catalyst and inhibitors	
3.1.1	Dangerous ingredients	No data available. name: Octamethylcyclotetrasiloxane Concentration: 0,01 - <0,1% CAS-N.: 556-67-2 EC No. 209-136-7 REACH Registration No. 01-2119529238-36-XXXX M-factor: Aquatic toxicity (chronic): 10 Indications: PBT, vPvB. All concentrations are given as percentages by weight if the ingredient is not a gas. Gas concentrations are given as volume percent. #Occupational exposure limits exist for this substance. PBT: Persistent, bioaccumulative and toxic substance. vPvB: Very persistent and very bioaccumulative substance. Classification Chemical name: Octamethylcyclotetrasiloxane Classification :Flam. Liq.: 3: H226; Repr.: 2: H361f; Aquatic Chronic: 1: H410; Indications: No data available.	

	:	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 occ
	Skin contact:	Wash with soap and water. 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	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

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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	All standard extinguishing agents suitable
	Unsuitable extinguishing media:	Avoid direct water jets; this will scatter and spread the fire.
5.2	Special hazards arising from the substance or mixture:	In case of fire, formation of carbon monoxide and carbon dioxide possible.
5.3	Advice for firefighters Advice for firefighters:	Keep away from sources of ignition - Do not smoke.
	Special protective equipment for fire fighting:	Wear self-contained breathing apparatus and protective clothing. Do not allow runoff from firefighting materials, even in diluted form, to reach bodies of water, sewers, or drinking water reservoirs. Use ordinary firefighting measures; consider hazards from other materials involved.

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:	Wipe up spilled material and take to a safe place. Caution: Contaminated surfaces can be slippery.
6.4	Reference to other sections:	Caution: Contaminated surfaces may be slippery. Do not allow runoff to reach drains, sewers or bodies of water. For personal protective equipment, see section 8 of the SDS.

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	Section 7: Handling and storage:		
7.1	Protective measures for safe handling:	The product may become electrostatically charged during decanting or decanting. Keep away from food, drink and animal feeding stuffs. Use only in well ventilated areas. Keep container tightly closed.	
	Notes on fire and explosion protection:	Keep away from sources of ignition - Do not smoke. Store in the original container.	
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.	
	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: Exposu	re controls/personal protective equipment
8.1	Parameters to be monitored Occupation 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:	Eye showers and emergency showers must be available in the workplace. Provide adequate general and local exhaust ventilation system.
	Individual protective measures, for exam	pple personal protective equipment
	General information:	Eye wash bottle with pure water. Do not eat, drink or smoke while working. Wash hands after handling.
	Eye/face protection:	Safety goggles with side protection according to EN 166
	Skin protection Hand protection:	Note: There is no risk of contact with chemicals. Use hand protection to avoid mechanical injuries.
	Other:	Wear suitable protective clothing and safety goggles/face protection when working.
	Respiratory protection:	Under ordinary conditions of use and with adequate ventilation, protective clothing is not normally required.
	Hygiene measures:	Observe recognized industrial hygiene measures. Do not eat, drink or smoke while working. Maintain good personal hygiene. Thoroughly clean hands and contaminated work areas with soap and water before leaving the workplace. Avoid contact with skin and eyes.
	Limitation and monitoring of environmental exposure:	There are no data available.

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	SECTION 9: Physical and chemical properties		
9.1	Information on the basic physical and chemical properties		
	Parameter	Value	
	State of aggregation	liquid / Paste	
	Colour	colorless	
	Smell	Odorless	
	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	here are no data available.	
	Decomposition temperature	The material is stable under normal conditions.	
	pH value	Not applicable	
	Kinematic viscosity	here are no data available.	
	Solubility	Löslichkeit in Wasser: Unlöslich	
		Löslichkeit (andere):	
		Löslich in Toluol	
	Partition coefficient n-octanol/water (log value)	here are no data available.	
	Vapour pressure	< 5 hPa (20 °C) (EG A4)	
		< 15 hPa (50 °C) (EG A4)	
	Density and/or specific gravity	1,13 g/cm3 (20 °C)	
	Relative vapour density	here are no data available.	
	Particle properties	here are no data available.	
9.2.	Other information here are no data available.		

	SECTION 10: Stability and reactivity		
10.1	Reactivity	No hazardous reaction when used as directed.	
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	Keep away from heat, sparks and open flame.	
10.5	Incompatible materials	None known.	

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Carbon oxides Silicon oxides. Measurements at temperatures above 150

	Decomposition products	°C in the presence of air (oxygen) have shown that small amounts of formaldehyde are formed by oxidative degradation.
		SECTION 11: Toxicological data
11.1	Information on hazard classes wit	hin the meaning of Regulation (EC) No 1272/2008
Our experience shows that our Cilepron electomer products a		

	SECTION 1	1: Toxicological data	
11.1	Information on hazard classes within the meaning	ng 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): 126,315.79 mg/kg	
	Serious eye damage/irritation	here are no data available.	
	Sensitisation of the respiratory tract/skin	Not classified for acute toxicity based on available data.	
	Germ cell mutagenicity	No data available. Specific substance(s) Octamethylcyclotetrasiloxane Ames test (OECD Guideline 471 (Genetic Toxicology: Salmonella typhimurium, Reverse Mutation Assay)): negative (not mutagenic) Mouse Lymphoma Test (OECD Guideline 476): negative (not mutagenic).	
	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	Fish		
		Product: No data available.		
		Aquatic invertebrates		
		Product: No data available.		

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		decomposes by processes naturally occurring in the atmosphere. Residues of D4 in air that do not decompose in this manner are not expected to be deposited from there in water, soil, or living organisms.
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	here are no data available. 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.	

	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:	This product is not a dangerous good according to the currently valid national and international dangerous good regulations. Keep separate from food and beverages.	
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	15.1 Safety, health and environmental regulations/specific legislation for the substance or mixture:		
	EU regulations		

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	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			
٠	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	Ordinance on Installations for Handling Substances Hazardous to Water (AwSV) WGK 1: slightly hazardous to water.			
		Classification according to AwS\ 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			

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	SECTION 16: Other information		
16.1	Information on the revision	Not relevant.	
	Important literature references and data sources:	The partition coefficient of D4 between PDMS and water was determined as log KPDMS-water =7.09. It follows that PDMS containing up to 3%w/w D4 produces a limiting thermodynamic concentration of 2.4 µg D4/L in the water phase. The critical 21d NOEC for daphnia of 7.9 µg D4/L is not reached. Therefore, the product is not classified for chronic aquatic toxicity.	
	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.	