Safety	Data Sheets			
•	U	n (EC) No 1907/2006 (F egulation (EU) No 2020	,.	
Silasto Article	® 50 no.: No. 97402_/	Ą		dr. hinz dental
Revise	d on:	15.05.2023		
Versior	n: 4.0	Replaced version:	3.0	
	SECTION 1: Ide	ntification of the substance	e or mixture and of th	e company/undertaking
1.1	Product identifier	Silasto® 50 Article no.: 97	402_A	
1.2	Relevant identified u	ses of the substance or mixtu	re and uses which are n	ot 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 The product has not been classified	mixture as hazardous according to the legislation in force.
2.1.1	Classification according to (EC) R Not classified	egulation 1272/2008 as amended.
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.

Safety Data	Sheets			
	-	(EC) No 1907/2006 (F gulation (EU) No 2020	-	
Silasto® 50 Article no.: I	No. 97402_A			dr.hinz dental
Revised on:		15.05.2023		
Version:	4.0	Replaced version:	3.0	

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.Chemicalname: OctamethylcyclotetrasiloxaneConcentration: 0,01 - <0,1%

	:	Section 4: First aid measures
4.1	Description of the first aid measures	3
	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	Indications for immediate medical he	elp 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.

Safety Data Sheets		
Complies with Regulation (EC) No 190 amended according to Regulation (EU)		
Silasto® 50 Article no.: No. 97402_A Revised on: 15.05.2023		dr.hinz dental
	version: 3.0	
5.1 General fire hazards	Fire residues and contaminated extin accordance with local official regulation	guishing water must be disposed of in ons.
Extinguishing agent Suitable extinguishing media	All standard extinguishing agents suit	able
Unsuitable extinguishing media:	Avoid direct water jets; this will scatte	er and spread the fire.
5.2 Special hazards arising from the substance or mixture:	In case of fire, formation of carbon me	onoxide 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:	0 11	
SECTION	N 6: Accidental release measure	S

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.

Safety	v Data Sheets		
	es with Regulation (EC) No 1907/2006 ed according to Regulation (EU) No 20	· · · ·	
	no.: No. 97402_A		dr. hinz dental
Revise			
Versio	n: 4.0 Replaced version	n: 3.0	
	Section 7: L	landling and storage:	
7.1	Protective measures for safe handling:	The product may become e decanting.	electrostatically charged during decanting or and animal feeding stuffs. Use only in well tainer tightly closed.
	Notes on fire and explosion protection:	Keep away from sources of original container.	ignition - Do not smoke. Store in the
7.2	Conditions for safe storage taking into account incompatibilities:	Store the product in the orig cool place.	ginal tightly closed container in a dry and
	Storage stability:	The material is stable under	r normal conditions.
	Storage class:	(TRGS 510): 12	
7.3	Specific end uses:	There are no data available	

	SECTION 8: Expo	sure controls/personal protective equipment
8.1	Parameters to be monitored Occupat exposure limit values	ional Occupational exposure limits do not apply to any of the ingredients.
	Biological limit values	None(s).
8.2	Exposure controls Suitable engineeri controls:	ing Eye showers and emergency showers must be available in the workplace. Provide adequate general and local exhaust ventilation system.
	Individual protective measures, for ex	xample 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.

Safety Data Sheets

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

	-	o® 50 e no.:	0 : No. 9740	2_A
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Revised on: Version: 4.0 15.05.2023 Replaced version: 3.0



_		and chemical properties	
Information on the basic physical and chemical propert			
	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)	
	Density and/or specific gravity	< 15 hPa (50 °C) (EG A4) 1,13 g/cm3 (20 °C)	
	Relative vapour density	here are no data available.	
	Particle properties	here are no data available.	
_	Other information		

SECTION 10: Stability and reactivity 10.1 No hazardous reaction when used as directed. Reactivity 10.2 The material is stable under normal conditions. Chemical stability 10.3 Dangerous polymerization does not take place. Possibility of hazardous reactions 10.4 Keep away from heat, sparks and open flame. Conditions to avoid 10.5 None known. Incompatible materials

Safety	y Data Sheets			
Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878				
Silasto® 50 Article no.: No. 97402_A			dr.hinz dental	
Revise	ed on:	15.05.2023		
Version: 4.0 Replaced version: 3.0			sion: 3.0	
10.6	10.6 Decomposition products			Measurements at temperatures above 150 en) have shown that small amounts of idative degradation.

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): 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.		

Safetv	Safety Data Sheets					
	Complies with Regulation (EC) No 1907/2006 (REACH), Annex II,					
-	ed according to Regulation (EU)					
Silasto	b® 50					
Article	no.: No. 97402_A	dr.hinz dental				
Revise	d on: 15.05.2023	dr. dental				
Versio		ersion: 3.0				
		Chronic toxicity				
		Fish				
		Product: No data available.				
		Aquatic invertebrates				
		Product: No data available.				
		Toxicity to aquatic plants				
12.2	Persistence and degradability	Product: No data available. Biodegradation				
		Product: No data available.				
		Specific substance(s): Octamethylcyclotetrasiloxane.				
		(20 d. 240 Baady Biodegradebility, CO, in Scaled Vessels (Headeness Test));				
		(29 d, 310 Ready Biodegradability - CO ₂ in Sealed Vessels (Headspace Test)): 3.7% Persistent Not readily biodegradable.				
		BOD/COD ratio				
		ProductNo data available.				
		Specific substance(s): Octamethylcyclotetrasiloxane				
		No data available.				
12.3	Bioaccumulative potential	Product: No data available.				
		Specific substance(s): Octamethylcyclotetrasiloxane				
		Thick head minnow, Bioconcentration Factor (BCF): 12.40				
12.4	Mobility in soil	No data available. Known or predicted distribution in environmental compartments.				
12.5	Octamethylcyclotetrasiloxane: No data are available. 2.5 Results of the PBT and vPvB No data available.					
.2.0	assessment					
		Octamethylcyclotetrasiloxane: Persistent, Bioaccumulative and Toxic (PBT), Very Persistent and Very Bioaccumulative (vPvB)Octamethylcyclotetrasiloxane				
		(D4) meets the current criteria of Annex XIII of the EU REACH Regulation for				
		PBTs and vPvBs and has been placed on the Candidate List of Substances of Very High Concern (SVHCs).,However, our understanding of the state of the				
		science is that D4 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 indicates that				
		D4 is not biomagnifying in aquatic and terrestrial food chains. D4 in air				

Safety	Safety Data Sheets				
•	es with Regulation (EC) No 1907 ed according to Regulation (EU)				
Silasto® 50 Article no.: No. 97402_A					
Revise	d on: 15.05.2023				
Versior	n: 4.0 Replaced v	ersion: 3.0			
		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	ΙΑΤΑ	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 Safety, health and environmental regulations/specific legislation for the substance or mixture:			
	EU regulations		

Safety I	Data Sheets			
	•	on (EC) No 1907/2006 (REACH), Annex II, Regulation (EU) No 2020/878		
Silasto® Article n) 50 no.: No. 97402 ₋	_ A	dr.hinz dental	
Revised	on:	15.05.2023		
Version:	4.0	Replaced version: 3.0		
	Regulation 1005/20 Controlled substan	009/EC on substances that deplete the ozone layer, Annex I, ces:	none	
	Regulation (EU) 20 amended:	19/1021 on persistent organic pollutants (new edition), as	none	
	Regulation (EC) No	9 649/2012 on the export and import of dangerous chemicals	: none	
	Regulation (EC) No authorisation, as ar	9 1907/2006, REACH Annex XIV List of substances subject t nended:	o none	
	EU. REACH Candia authorisation:	date List of Substances of Very High Concern (SVHC) for	none	
		o 1907/2006 Annex XVII Restrictions on the manufacture, ket and use of certain dangerous substances, preparations a	none nd	
	Directive 2004/37/E	EC on the protection of workers from the risks related to ogens or mutagens at work:	none	
	in the safety and he	C on the introduction of measures to encourage improvemer ealth at work of pregnant workers and workers who have or are breastfeeding:	none	
		U (Seveso III) on the control of major-accident hazards	none	
) No 166/2006 concerning the establishment of a European and Transfer Register, ANNEX II: Pollutants	none	
	Directive 98/24/EU agents at work:	on the protection of workers from the risks related to chemic	al none	
	National regulatio	ns		
	Water hazard class Ordinance on Installations for Handling Substances Hazar to Water (AwSV) WGK 1: sl hazardous to water.			
			Classification according to AwSV, Annex 1 (5.2)	
	Reference to Tech	nical Rules for Hazardous Substances (TRGS)	Technical Instructions on Air Quality Control (TA-Luft):	
		Octamethylcyclotetrasiloxane		
	VOC Directive (100	10(42/EC) and the Decension Directive (2004/42/EC)	Number 5.2.5 Class II, Organic substances	
		99/13/EC) and the Decopaint Directive (2004/42/EC)	none	
	Other regulations		none	
15.2	Chemical safety a	ssessment	No chemical safety assessment has been carried out.	

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Sare	ety Data Sheets		
	plies with Regulation (EC) No 19 nded according to Regulation (E		
	sto® 50 sle no.: No. 97402_A	dr.hinZ dental	
Revi	sed on: 15.05.202	3	
Version: 4.0 Replaced version: 3.0			
	S	ECTION 16: Other information	
16.1	Information on the revision	Not relevant.	
	Important literature references and	· ·	PDMS and water was determined as log

data sources:	KPDMS-water =7.09. It follows that PDMS containing up to 3%w/w D4 produces 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 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

Safety	Safety Data Sheets						
Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878							
Silasto® 50 Article no.: No. 97402_B				dr.hinz dental			
Revise	d on:	15.05.2023					
Versior	n: 4.0	Replaced version:	3.0				
	SECTION 1: Ide	ntification of the substand	e or mixture and of the	e company/undertaking			
1.1	Product identifier Silasto® 50 Article no.: 97402_B						
1.2	Relevant identified uses of the substance or mixture and uses which are not recommended						
1.2.1	1.2.1 Relevant uses medical device: Silikon Elastomer (B)						

Uses that are not recommended:	None known
Details of the supplier providing the safety data sheet	Dr. Hinz Dental Vertriebsgesellschaft mbH & Co. KG
,	Friedrich der Große 64
	44628 Herne
	440201161116
	CERMANIX
	GERMANY
	Phone: + 49 (0) 23 23 / 59 34 20
	Fax: + 49 (0) 23 23 / 59 34 29
	E-Mail: qm@dhug.de
Emorgonov numbor	Contact: Dr. P. Hinz
Emergency number	
	Phone: + 49 17 51 83 41 34

SECTION 2: Possible dangers

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

	SECTION 3: Composition / Information on ingredients		
		Vinyl group-containing polydimethylsiloxane with fillers, crosslinker and inhibitor.	
3.1.1	Dangerous ingredients	No hazardous ingredients.	

Safety	Safety Data Sheets			
	Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878			
Silasto® 50 Article no.: No. 97402_B			dr.hinZ dental	
Revise	d on: 15.05.2023			
Versior	n: 4.0 Replaced	version: 3.0		
	Se	ection 4: First aid measures		
4.1	Description of the first aid measures			
	General notes	No action should be taken that involv adequately trained.	es personal risk or has not been	
	Inhalation:	Remove to fresh air. Seek medical a	ttention if symptoms occur.	
	Eye contact:	Immediately flush eye with water. Se	ek medical attention if symptoms occ	
	Skin contact:	Wash the area with soap and water. Seek medical attention if symptoms of	Remove contaminated, soaked clothing. occur.	
	Ingestion:	Do NOT induce vomiting if swallowed medical attention.	d. Administer a glass of water. Seek	
4.2	Most important symptoms and effects, both acute and delayed:	not known		
4.3	3 Indications for immediate medical help or special treatment			
	Dangers:	This product is not expected to be happeneous personal hygiene.	rmful under normal use and proper	
	Treatment:	Do NOT induce vomiting if swallowed	d. Administer a glass of water.	

	SEC	TION 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.

Safety Data Sheets

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

Silasto® 50 Article no.: No. 97402_B

Revised on:15.05.2023Version:4.0Replaced version:3.0



	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		
		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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Safety Data Sheets		
Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878		
Silasto® 50 Article no.: No. 97402_B		dr.hinzdental
Revised on: 15.05.2023		
Version: 4.0 Replaced v	ersion: 3.0	
Skin protection Hand protection:	Note: There is no risk of contact wit mechanical injuries.	th chemicals. Use hand protection to avoid
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 h	

	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	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:	
	Decomposition tomperature	435 °C The material is stable under normal conditions.	
	Decomposition temperature		
	pH value	Not applicable	
	Kinematic viscosity	< 4.200 mm2/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/cm3 (20 °C) (DIN 51757)	
	Relative vapour density	here are no data available.	
	Particle properties	here are no data available.	

Safety Data Sheets Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878 Silasto® 50 Article no.: No. 97402_B Revised on: 15.05.2023 Version: 4.0 Replaced version: 3.0

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.	

Safety	Data Sheets			
•	•	n (EC) No 1907/2006 (Regulation (EU) No 202		
Silasto Article	® 50 no.: No. 97402_	В		dr.hinz dental
Revise	d on:	15.05.2023		
Version	n: 4.0	Replaced version:	3.0	
		SECTION 11	: Toxicological data	
11.1	Information on haza	rd classes within the meaning	g of Regulation (EC) No 1	272/2008
	acute toxicity		be handled without any	that our Silopren elastomer products can y health hazards if they are handled properly n the usual working hygiene.
	Corrosive/irritant effe	ct on the skin	ATEmix (estimated act mg/kg	ute toxicity of the mixture): 115,384.62
	Serious eye damage/	irritation	here are no data availa	able.

	Corrosive/irritant effect on the skin	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	

	Cofety Data Chasta				
Safety	Safety Data Sheets				
-	Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878				
	Silasto® 50 Article no.: No. 97402_B				
Revise	ed on: 15.05.2023				
Versio	n: 4.0 Replaced ve	ersion: 3.0			
L					
		Product: No data available.			
		Toxicity to aquatic plants			
		Product: No data available. no data	a 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 of REACH	contain any components that are subject to		
		Article 57(f) or the Delegated Regu	ulation (EU) 2017/2100 of the		
		Commission or Commission Deleg	ated 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 produ	ict 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.	

Safety Data Sheets Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878 Silasto® 50 Article no.: No. 97402_B Revised on: 15.05.2023 Version: 4.0 Replaced version: 3.0

	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	ΙΑΤΑ	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		
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	1	

Safety I	Data Sheets	
•	s with Regulation (EC) No 1907/2006 (REACH), Annex II, d according to Regulation (EU) No 2020/878	
Silasto® Article r	9 50 no.: No. 97402_B	dr.hinz dental
Revised	on: 15.05.2023	
Version:	4.0 Replaced version: 3.0	
		1
	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.