

**Safety Data Sheets 1907/2006/EG - REACH (DE)****Bruxi+ starter set**  
**Article no.: No. 93805**Revised on: 16.05.2022  
Version: 3.0 Replaced version: 2.0**SECTION 1: Identification of the substance or mixture and of the company/undertaking**

1.1	<b>Product identifier</b>	<b>Bruxi+ starter set</b> <b>Article no.: 93805</b>
1.2	<b>Relevant identified uses of the substance or mixture and uses which are not recommended</b>	
1.2.1	<b>Relevant uses medical device:</b>	Medical device - oral vestibule plate
1.2.2	<b>Uses that are not recommended:</b>	None known
1.3	<b>Details of the supplier providing the safety data sheet</b>	<b>Dr. Hinz Dental Vertriebsgesellschaft mbH &amp; Co. KG</b>  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	<b>Emergency number</b>	Contact: <b>Dr. P. Hinz</b> Phone: + 49 17 51 83 41 34

**SECTION 2: Possible dangers**

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

**SECTION 3: Composition / Information on ingredients**

3.1	<b>Chemical characterisation</b>	Vinyl group-containing polydimethylsiloxane with platinum catalyst and inhibitors.
3.1.1	<b>Dangerous ingredients</b>	No hazardous ingredients.

**Section 4: First aid measures**

4.1	<b>Description of the first aid measures</b>	
	<b>General notes</b>	No action should be taken that involves personal risk or that has not been adequately trained.

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	<b>Inhalation:</b>	Remove to fresh air. Seek medical attention if symptoms occur.
	<b>Eye contact:</b>	Immediately flush eye with water. Seek medical attention if symptoms occur.
	<b>Skin contact:</b>	Wash with soap and water. Seek medical attention if symptoms occur.
	<b>Ingestion:</b>	Do NOT induce vomiting if swallowed. Administer a glass of water. Get medical help.
4.2	<b>Most important symptoms and effects, both acute and delayed:</b>	None known.
4.3	<b>Indications for immediate medical help or special treatment</b>	
	<b>Dangers:</b>	This product is not expected to be harmful under normal use and adequate personal hygiene.
	<b>Treatment:</b>	Do NOT induce vomiting if swallowed. Administer a glass of water.

**SECTION 5: Fire-fighting measures**

5.1	<b>General fire hazards</b>	Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.
	<b>Extinguishing agent</b> <b>Suitable extinguishing media</b>	Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.
	<b>Unsuitable extinguishing media:</b>	Avoid direct water jet; this will disperse and spread the fire
5.2	<b>Special hazards arising from the substance or mixture:</b>	In case of fire, formation of carbon monoxide and carbon dioxide possible..
5.3	<b>Advice for firefighters</b> <b>Advice for firefighters:</b>	Keep away from sources of ignition - Do not smoke .
	<b>Special protective equipment for fire fighting:</b>	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	<b>Personal precautions, protective equipment and emergency procedures:</b>	Remove all sources of ignition. Wear personal protective equipment.
6.2	<b>Environmental protection measures:</b>	Do not allow the runoff to enter the sewer system, waterways or soil
6.3	<b>Methods and material for retention and cleaning:</b>	Wipe up spilled material and take to a safe place. Caution: Contaminated surfaces may be slippery.
6.4	<b>Reference to other sections:</b>	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 SDS.

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7.1	<b>Protective measures for safe handling:</b>	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.
	<b>Storage conditions:</b>	Keep away from sources of ignition - Do not smoke. Store in original container
7.2	<b>Conditions for safe storage taking into account incompatibilities:</b>	Store the product in the original tightly closed container in a dry and cool place.
	<b>Storage stability:</b>	The material is stable under normal conditions.
	<b>Storage class:</b>	Flammable liquids that cannot be assigned to any of the above LGKs
7.3	<b>Specific end uses:</b>	There are no data available.

**SECTION 8: Exposure controls/personal protective equipment**

8.1	<b>Parameters to be monitored Occupational exposure limit values</b>	Occupational exposure limits do not apply to any of the ingredients
	<b>Biological limit values</b>	None(s).
8.2	<b>Exposure controls Suitable engineering controls:</b>	Eye showers and emergency showers must be available in the workplace. Provide adequate general and local exhaust ventilation system.
	<b>Individual protective measures, for example personal protective equipment</b>	
	<b>General information:</b>	Eye wash bottle with pure water. Do not eat, drink or smoke while working. Wash hands after handling
	<b>Eye/face protection:</b>	Safety goggles with side protection according to EN 166
	<b>Skin protection Hand protection:</b>	Note: There is no risk of contact with chemicals. Use hand protection to avoid mechanical injuries.
	<b>Other:</b>	Wear suitable protective clothing and goggles/face protection when working.
	<b>Respiratory protection:</b>	Under ordinary conditions of use and with adequate ventilation, protective clothing is not normally required.
	<b>Hygiene measures:</b>	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.
	<b>Limitation and monitoring of environmental exposure:</b>	There are no data available.

**SECTION 9: Physical and chemical properties**

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<b>9.1</b>	Information on the basic physical and chemical properties	
	<b>Parameter</b>	<b>Value</b>
	State of aggregation	liquid
	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	There are no data available.
	Lower explosion limit upper explosion limit	There are no data available. Es liegen keine Daten vor.
	Flash point	> 100 °C
	Ignition temperature	There are no data available.
	Decomposition temperature	The material is stable under normal conditions.
	pH value	Not applicable
	Kinematic viscosity	Not applicable
	Solubility	Insoluble in water Soluble in toluene
	Partition coefficient n-octanol/water (log value)	There 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/cm <sup>3</sup> (20 °C)	
Relative vapour density	There are no data available.	
Particle properties	There are no data available.	
<b>9.2.</b>	<b>Other information</b> There are no data available.	

### SECTION 10: Stability and reactivity

<b>10.1</b>	<b>Reactivity</b>	There are no data available.
<b>10.2</b>	<b>Chemical stability</b>	The material is stable under normal conditions
<b>10.3</b>	<b>Possibility of hazardous reactions</b>	Dangerous polymerization does not take place.
<b>10.4</b>	<b>Conditions to avoid</b>	Keep away from heat, sparks and open flame.
<b>10.5</b>	<b>Incompatible materials</b>	None known.
<b>10.6</b>	<b>Decomposition products</b>	Carbon oxides Silicon oxides. Measurements at temperatures above 150 °C in the presence of air (oxygen) have shown that formaldehyde is formed in small quantities by oxidative degradation.

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**SECTION 11: Toxicological data**

11.1	<b>Information on hazard classes within the meaning of Regulation (EC) No 1272/2008</b>	
	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 normal working hygiene.
	Corrosive/irritant effect on the skin	There are no data available
	Serious eye damage/irritation	There are no data available
	Sensitisation of the respiratory tract/skin	There are no data available
	Germ cell mutagenicity	There are no data available
	Carcinogenicity	There are no data available
	Reproductive toxicity	There are no data available
	Specific target organ toxicity at single exposure	There are no data available
	Specific target organ toxicity in case of repeated exposure	There are no data available
	Aspiration hazard	There are no data available
11.2	<b>Information on other hazards</b>	
	There are no data available	
11.2.1	<b>Endocrine disrupting properties</b>	
	There are no data available	
11.2.2	<b>Other information</b>	
	There are no data available	

**SECTION 12. Environmental information**

12.1	<b>Toxicity</b>	There are no data available
12.2	<b>Persistence and degradability</b>	There are no data available
12.3	<b>Bioaccumulative potential</b>	There are no data available
12.4	<b>Mobility in soil</b>	There are no data available
12.5	<b>Results of the PBT and vPvB assessment</b>	There are no data available
12.6	<b>Endocrine disrupting properties</b>	There are no data available
12.7	<b>Other adverse effects</b>	There are no data available

**SECTION 13: Disposal instructions**

13.1	<b>Waste treatment process</b>	
	<b>General information</b>	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.
	<b>Disposal methods</b>	Can be incinerated as long as this 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	<b>Safety, health and environmental regulations/specific legislation for the substance or mixture:</b>	
	<b>EU regulations</b>	
	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
	<b>National regulations</b>	
	Water hazard class	Ordinance on Installations for Handling Substances Hazardous to Water (AwSV).

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		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	none
<b>15.2</b>	<b>Chemical safety assessment</b>	No chemical safety assessment has been carried out.

**SECTION 16: Other information**

<b>16.1</b>	<b>Information on the revision</b>	Not relevant.
	<b>Important literature references and data sources:</b>	There are no data available.
	<b>Training information:</b>	There are no data available.
	<b>Disclaimer:</b>	<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>