


<p>Safety Data Sheets</p> <p>Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878</p> <p>OrthoPreventAligner® KL II-M hart Article no.: No. 90922</p> <p>Revised on: 15.05.2023 Version: 4.0 Replaced version: 3.0</p>	
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SECTION 1: Identification of the substance or mixture and of the company/undertaking		
1.1	Product identifier	OrthoPreventAligner® KL II-M hart Article no.: 90922
1.2	Relevant identified uses of the substance or mixture and uses which are not recommended	
1.2.1	Relevant uses medical device:	Medical device - oral vestibule plate
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	Classification according to Regulation (EC) No 1272/2008: Not a hazardous substance or mixture
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	The product contains substances relevant for the assessment in section 12.5. Product may release hydrogen. Risk of hydrogen formation with water, alcohols, acids, metal salts, amines and alkalis. The hydrogen formed may form oxyhydrogen gas in combination with oxygen.

SECTION 3: Composition / Information on ingredients		
3.1	Chemical characterisation	Polydimethylsiloxane and excipient

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3.1.1	Dangerous ingredients	The product contains no hazardous ingredients above the consideration limit(s). CAS No. 540-97-6 Substance: dodecamethylcyclohexasiloxane Content(%) ≥ 0.1 - < 0.3 Reason for inclusion: Persistent, bioaccumulative and toxic (Article 57d) Very persistent and very bioaccumulative (Article 57e) CAS No. 541-02-6 Substance: decamethylcyclopentasiloxane Content(%) ≥ 0.1 - < 0.3 Reason for inclusion: Persistent, bioaccumulative and toxic (Article 57d) Very persistent and very bioaccumulative (Article 57e)
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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 (show label or MSDS if possible).
	Inhalation:	Product cannot be inhaled under normal circumstances.
	Eye contact:	Rinse immediately with plenty of water. If irritation persists, seek medical advice.
	Skin contact:	Remove product with cloth or paper. Wash off with plenty of water or soap and water. In case of visible skin lesions or discomfort, seek medical advice (show label or MSDS if possible).
	Ingestion:	Have plenty of water drunk in small portions. Do not induce vomiting.
4.2	Most important symptoms and effects, both acute and delayed:	Relevant information is located in other parts of this section.
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	Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.
	Extinguishing agent Suitable extinguishing media	Fires can be controlled with water mist, foam or carbon dioxide. Larger fires are best fought with alcohol-resistant, water film-forming foam agents (AFFF-AR).

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	Unsuitable extinguishing media:	Water jet , extinguishing powder , halon
5.2	Special hazards arising from the substance or mixture:	In case of fire, generation of hazardous combustion gases or vapors possible. Exposure to combustion products may be a health hazard! Hazardous fire products: toxic and very toxic fumes . When using Caution should be exercised when using water-based extinguishing agents, as hydrogen may be released which, after extinguishing the can accumulate in poorly ventilated or confined areas and lead to renewed fire formation or explosions. explosions. Foam carpets may also trap hydrogen or flammable vapors, which can cause ground explosions can occur. Eliminate ignition sources during cleaning and pickup.
5.3	Advice for firefighters Advice for firefighters:	Fires involving SiH polysiloxane materials may be difficult to extinguish.
	Special protective equipment for fire fighting:	Use self-contained breathing apparatus. Keep unprotected persons away.

SECTION 6: Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures:	Secure the area. Wear personal protective equipment (see section 8). Keep unprotected persons away. If material has been released, draw attention to the danger of slipping. Do not walk through spilled material
6.2	Environmental protection measures:	Do not allow to enter waters, waste water and soil. Close leak if this can be done without risk. Retain contaminated water/extinguishing water. Dispose of in properly labeled containers. In case of leakage into water, sewage system or the subsoil, notify the competent authority.
6.3	Methods and material for retention and cleaning:	To avoid adhesion, dust the surface with sand or bleaching earth and pick up material mechanically. Sweep up or scrape up spilled material and place in a special chemical waste container. Remove the any remaining slippery coating with detergent / soap solution or other biodegradable cleaner. To Improve skid resistance, sand or other inert granular material. Additional Instructions: Vacuum fumes. Eliminate ignition sources. Observe explosion protection. Material for disposal must be kept away from incompatible materials according to point 10. Do not mix contaminated material with clean material. Do not seal collection vessels gas-tight. Observe the information in section 7.
6.4	Reference to other sections:	Relevant information in other sections must be observed. This applies in particular to information on personal protective equipment (section 8) and disposal (section 13).

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Section 7: Handling and storage:

7.1	Protective measures for safe handling:	Ensure good room and workplace ventilation. Open and handle containers with care. Keep containers not in use keep closed containers not in use. Keep away from incompatible substances according to point 10. If possible, make equipment inert and fill containers with nitrogen to reduce oxygen content. Further information on the safe handling of H-siloxanes is available from Wacker Chemie AG. Observe information in section 8.
	Notes on fire and explosion protection:	Store in a dry and cool place. Protect from moisture. Store container in a well-ventilated place.
7.2	Conditions for safe storage taking into account incompatibilities:	Requirements to be met by storerooms and containers: Do not store in containers made of virgin glass with alkaline surface. Observe local official regulations. Information about storage in one common storage facility: Do not store together with: basic substances (e.g. alkalis, ammonia, amines) , oxidizing agents , strong acids . Local observe local regulations
	Storage stability:	No information available.
	Storage class:	Storage class (TRGS 510): 10
7.3	Specific end uses:	No information available.

SECTION 8: Exposure controls/personal protective equipment

8.1	Parameters to be monitored Occupational exposure limit values	not applicable
	Biological limit values	None(s).
8.2	Exposure controls Suitable engineering controls:	Observe information in section 7. Observe national regulations.
	Individual protective measures, for example personal protective equipment	
	General information:	Observe general hygiene measures when handling chemical substances. Do not eat, drink or smoke during work.
	Eye/face protection:	Recommendation: Safety goggles
	Skin protection Hand protection:	When handling the product, the use of protective gloves is recommended, in accordance with recognized standards such as EN374. Recommended glove material: Protective gloves made of nitrile rubber. Material thickness: > 0.1 mm

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	<p>Breakthrough time: > 480 min</p> <p>Recommended glove material: Protective gloves made of butyl rubber</p> <p>Material thickness: > 0.3 mm</p> <p>Breakthrough time: > 480 min</p> <p>Please observe the specifications of the glove supplier with regard to permeability and breakthrough time. Also the specific, conditions under which the product is used, such as risk of cut, abrasion and contact time. contact duration. It should be noted that, in practice, the daily service life of a chemical protective glove may be (e.g. temperature) may be significantly shorter than the permeation time determined by testing.</p>
Other:	Wear suitable protective clothing and goggles/face protection when working.
Respiratory protection:	Normally no personal respiratory protection 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:	Do not allow to enter waters, waste water and soil.

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	Not determined
	Boiling point or initial boiling point and boiling range	Not applicable
	Flammability	No data known.
	Lower explosion limit upper explosion limit	not applicable
	Flash point	> 150 °C
	Ignition temperature	> 210 °C
	Decomposition temperature	> 250 °C
	pH value	not applicable
	Kinematic viscosity	> 9000000 mPa.s
	Solubility	practically insoluble
	Partition coefficient n-octanol/water (log value)	No data available.

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	Vapour pressure	Not applicable
	Density and/or specific gravity	No data available.
	Relative vapour density	1,17 (water / 4 °C = 1.00) (ISO 1183-1 A) 1.17 g/cm ³ (ISO 1183-1 A)
	Particle properties	Not applicable
9.2.	Other information	According to present knowledge, spontaneous ignition of SiH-containing products on a catalytically active catalytic substrate can occur at much lower temperatures than expected. This applies to porous or fibrous materials including those with alkaline surfaces such as thermal or cementitious insulating materials. Explosion limits for released hydrogen: 4 - 75.6 vol%. pH-value: Product reacts neutral.

SECTION 10: Stability and reactivity

10.1	Reactivity	No known hazardous reactions when stored and handled properly. Relevant information may be found in other parts of this section.
10.2	Chemical stability	No data
10.3	Possibility of hazardous reactions	No data
10.4	Conditions to avoid	Moisture, heat, open flames and other sources of ignition. Contact with contaminated pipelines and containers or with corroded or rusty containers may lead to increased formation of hydrogen. Observe information in section 7.
10.5	Incompatible materials	Proton-active substances. Reacts with acids, basic substances (e.g. alkalis, ammonia, amines), alcohols, water, moisture, oxidizing agents, catalysts. The reaction takes place with the formation of hydrogen
10.6	Decomposition products	In case of contact with substances mentioned under 10: Hydrogen. Measurements have shown that, at temperatures above approx. 150 °C a small amount of formaldehyde is released 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
11.1	acute toxicity	Exposure route Result/effect Species/test system Source Oral LD50: > 2000 mg/kg rat Conclusion by analogy dermal LD50: > 2000 mg/kg rat Conclusion by analogy Result/Effect Species/Test System Source
	Corrosive/irritant effect on the skin	No skin irritation Rabbit Analogy conclusion Result/Effect Species/Test System Source
	Serious eye damage/irritation	None Eye irritation Rabbit Analogy
	Sensitisation of the respiratory tract/skin	Exposure route Result/effect Species/test system Source dermal Does not cause skin sensitization. Guinea pig; Buehler test By analogy OECD 406
	Germ cell mutagenicity	No toxicological test data are available for this endpoint for the total product
	Carcinogenicity	Toxicological test data for the total product are not available for this endpoint.
	Reproductive toxicity	Toxicological test data for the total product are not available for this endpoint.
	Specific target organ toxicity at single exposure	Toxicological test data for the total product are not available for this endpoint.
	Specific target organ toxicity in case of repeated exposure	Toxicological test data for the total product are not available for this endpoint.
	Aspiration hazard	Due to the physico-chemical properties of the product, an aspiration hazard is not to be expected.
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	Evaluation based on ecotoxicological tests with similar products, taking into account the physical- chemical properties: No classification-relevant effects on aquatic organisms are expected for this product. According to current experience, no adverse effects in sewage treatment plants are to be expected.
12.2	Persistence and degradability	Silicone content: Non-biodegradable. Separation by sedimentation.
12.3	Bioaccumulative potential	Polymer component: No adverse effects expected.

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12.4	Mobility in soil	<p>Assessment:</p> <p>Silicone content: Insoluble in water.</p> <p>Data on substances:</p> <p>Decamethylcyclopentasiloxane (D5):</p> <p>D5 has very low solubility in water, evaporates rapidly and diffuses into organic material. The substance is degraded in the atmosphere by reaction with hydroxyl radicals. From soil, D5 is eliminated by evaporation and hydrolysis, and by clay mineral catalyzed degradation.</p> <p>Dodecamethylcyclohexasiloxane (D6):</p> <p>D6 has very low water solubility, evaporates rapidly and diffuses into organic material. The substance is degraded in the atmosphere by reaction with hydroxyl radicals. From soil, D6 is eliminated by evaporation and hydrolysis, as well as by degradation catalyzed by clay minerals.</p>
12.5	Results of the PBT and vPvB assessment	<p>The product contains substances "\leq 0.1%, which are subject to the SVHC process according to REACH Regulation (EC) No 1907/2006 Art. 57 as they meet the PBT and/or VPVB criteria according to REACH Regulation (EC) No 1907/2006, Annex XIII.</p> <p>Data on substances:</p> <p>Decamethylcyclopentasiloxane (D5):</p> <p>D5 formally meets the criteria for vPvB substances according to Regulation (EC) No 1907/2006 (REACH), Annex XIII. However, D5 does not behave like known VPVB substances. Scientific field studies show that D5 does not accumulate in the aquatic or terrestrial food chain. In the air, D5 is degraded by reaction with naturally occurring hydroxyl radicals. Uneliminated D5 from the air is not expected to enter water, soil, or living organisms.</p> <p>Dodecamethylcyclohexasiloxane (D6):</p> <p>D6 formally meets the criteria for vPvB substances under Regulation (EC) No. 1907/2006 (REACH), Annex XIII; however, D6 does not behave like known VPVB substances. Scientific field studies show that D6 does not accumulate in the aquatic or terrestrial food chain. In the air, D6 is degraded by reaction with naturally occurring hydroxyl radicals. Uneliminated D6 from the air is not expected to enter water, soil, or living organisms.</p>
12.6	Endocrine disrupting properties	There are no data available
12.7	Other adverse effects	There are no data available

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SECTION 13: Disposal instructions

13.1	Waste treatment process	
	General information	<p>Product Recommendation: Danger of oxyhydrogen gas formation in case of contact with substances mentioned in 10. Material intended for disposal must be kept incompatible substances mentioned in point 10. Waste from this product should not be mixed with other waste. mixed with other wastes. Waste containers must be equipped with pressure equalization devices such as ventilated lids. be equipped. Material that cannot be reused, reprocessed or recycled should be disposed of at an approved facility in accordance with national, state and local regulations. Depending on regulations, waste treatment methods may include Waste treatment methods may include, for example, landfill disposal or incineration Uncleaned packaging. Recommendation: Containers may contain hazardous levels of hydrogen. Do not reuse uncleaned containers or fill them with other materials materials due to possible reaction between residual product and incompatible material. Containers must be completely empty (drip-free, free-flowing, spatula clean). Packaging must be disposed of in accordance with the national regulations in force, packaging should preferably be reused or recycled. Packaging that cannot be packaging must be disposed of in the same way as the substance.</p>
	Disposal methods	<p>No waste code number according to the European Waste Catalogue (AVV) can be defined for this product, since only the intended only the intended use by the consumer allows an assignment. The waste code number must be defined within the in consultation with the waste disposal company.</p>

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:	Relevant information in other sections must be observed
14.7	Carriage in bulk in accordance with Annex II of the MARPOL Convention and the IBC Code:	There is no intention to carry bulk cargo in tankers.

SECTION 15: Legislation

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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:	Not applicable
	Regulation (EU) 2019/1021 on persistent organic pollutants (new edition), as amended:	Not applicable
	Regulation (EC) No 649/2012 on the export and import of dangerous chemicals:	Not applicable
	Regulation (EC) No 1907/2006, REACH Annex XIV List of substances subject to authorisation, as amended:	REACH Annex XVII: This product contains decamethylcyclopentasiloxane (D5) above 0.1% by weight. Annex XVII, entry 70 of Regulation 1907/2006 in current version has to be considered.
	EU. REACH Candidate List of Substances of Very High Concern (SVHC) for authorisation:	Not applicable
	Regulation (EC) No 1907/2006 Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles :	Not applicable
	Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work...:	Not applicable
	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:	Not applicable
	Directive 2012/18/EU (Seveso III) on the control of major-accident hazards involving dangerous substances:	Not applicable
	REGULATION (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register, ANNEX II: Pollutants	Not applicable
	Directive 98/24/EU on the protection of workers from the risks related to chemical agents at work:	Not applicable
	National regulations	
	Water hazard class	1 (VwVwS (Deutschland) vom 27.07.2005, Anhang 4)
Reference to Technical Rules for Hazardous Substances (TRGS)	Not applicable	
VOC Directive (1999/13/EC) and the Decopaint Directive (2004/42/EC)	Not applicable	
Other regulations	Information on the International Registration Status Where relevant information on individual substance inventories is available, it is listed below.	

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		<p>Australia : AICS (Australian Inventory of Chemical Substances):</p> <p>This product is not listed or not in compliance with the substance inventory.</p> <p>N</p> <p>Philippines..... : PICCS (Philippine Inventory of Chemicals and Chemical Substances):</p> <p>This product is not listed or not in compliance with the substance inventory.</p> <p>N</p> <p>United States of America (USA) : TSCA (Toxic Substance Control Act Chemical Substance Inventory):</p> <p>All components of this product are actively listed or in compliance with the substance inventory.</p> <p>TY</p> <p>Taiwan : TCSI (Taiwan Chemical Substance Inventory):</p> <p>This product is listed or in compliance with the substance inventory. General</p> <p>Note: Chemical law in Taiwan requires a Phase 1 registration for</p> <p>TCSI-listed or TCSI-compliant substances when imported into Taiwan or manufactured in Taiwan.</p> <p>manufacturing in Taiwan exceeds the quantity threshold of 100 kg/year (for mixtures</p> <p>(for mixtures, this must be calculated for each ingredient). The responsibility</p> <p>for this lies with the importer or manufacturer.</p>
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		<p>J</p> <p>European Economic Area (EEA) : REACH (Regulation (EC) No 1907/2006):</p> <p>General note: Registration obligations arising from manufacture in the</p> <p>EEA or import into the EEA by the supplier named in section 1 shall be fulfilled by the supplier.</p> <p>shall be fulfilled by the latter. Registration obligations arising from import into</p> <p>the EEA by customers or other downstream users shall be fulfilled by them.</p> <p>be fulfilled by them.</p> <p>South Korea (Republic of Korea)..... : AREC (Chemicals Registration and Evaluation Act; "K-REACH"):</p> <p>Please contact your regular WACKER contact person for further</p> <p>information.</p>
15.2	Chemical safety assessment	<p>The result of the chemical safety assessment does not require the specification of exposure scenarios and uses in the safety data sheet.</p>

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:	<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>