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

Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



1.1 Product identifier		Friedensstifter® KL II / Stufe 1	
		Article no.: 90984	
1.2	Relevant identified uses of the substance or mixture and uses which are not recommended		
1.2.1	Relevant uses medical device:	Relevant uses medical device: Medical device - test device	
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 No hazardous substance or mixture.	
2.1.1	Classification according to (EC) Re No hazardous substance or mixture.	
2.2	Labelling elements Additional information:	Not applicable No data available
2.3	Other dangers	This substance/mixture does not contain any components at concentrations of 0.1% or higher that are classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). Environmental information: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more. Toxicological information: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

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Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



SECTION 3: Composition / Information on ingredients		
3.1	Chemical characterisation	Vinylacetat-Ethylen-Copolymer
3.1.1	Dangerous ingredients	Chemical name: Vinyl Acetate - Ethylene Copolymer CAS No. EC No. INDEX No. Registration No.: 24937-78-8 Concentration (% w/w): > 98 For explanation of abbreviations, see section 16.

		Section 4: First aid measures
4.1	Description of the first aid measures	
	General notes	Do not leave affected person unattended.
	Inhalation:	If unconscious, apply stable side position and seek medical advice. If symptoms persist, consult a doctor.
	Eye contact:	Remove contact lenses. Protect uninjured eye.
		Consult a medical specialist if eye irritation persists.
	Skin contact:	After contact with the melted product, quickly cool affected skin area with water. Do not remove solidified product from skin. Burns must be treated by a doctor.
	Ingestion:	Keep airways clear. Do not administer milk or alcoholic beverages. Never give anything by mouth to a person who has fainted. Consult a physician if symptoms persist.
4.2	Most important symptoms and effects, both acute and delayed:	None known.
4.3	Indications for immediate medical help or special treatment	
	Dangers:	None known.
	Treatment:	Symptomatic treatment.

	SECTION 5: Fire-fighting measures		
5.1	General fire hazards	Usual measures for fires with chemicals.	
		Adapt extinguishing measures to the surroundings	
	Extinguishing agent		
	Suitable extinguishing media	Water	
		Foam	
		Dry chemical extinguishing agent	
		Carbon dioxide (CO2)	
	Unsuitable extinguishing media:	None known.t	

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Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



5.2	Special hazards arising from the substance or mixture:	Do not use a full stream of water to suppress dispersion and spread of fire
5.3	Advice for firefighters Advice for firefighters:	Hazardous combustion products: Oxides of carbon
	Special protective equipment for fire fighting:	In case of fire, wear self-contained breathing apparatus if necessary.

SECTION 6: Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures:	Avoid dust formation. Avoid inhalation of dust. Provide adequate ventilation.
6.2	Environmental protection measures:	No special environmental protection measures required.
6.3	Methods and material for retention and cleaning:	Pick up dust-free and deposit dust-free. Sweep and shovel up. Place in suitable and sealed containers for disposal.
6.4	Reference to other sections:	See sections: 7, 8, 11, 12 and 13.

	Section 7	7: Handling and storage:
7.1	Protective measures for safe handling:	Personal protective equipment see under section 8. Handling Do not eat, drink or smoke in the area of application. Keep dust generation and accumulation as low as possible. Advice on protection against fire and explosion Provide suitable ventilation in case of dust generation. When processing the product, dusts may form an explosive mixture with air. Hygiene measures General industrial hygiene measuren.
	Notes on fire and explosion protection:	Store in a cool and dry place. Maintain dryness of resin To maintain product quality, store away from heat and direct sunlight. Electrical equipment/appliances must comply with the state of the art in safety.
7.2	Conditions for safe storage taking into account incompatibilities:	Combined storage instructions No substances requiring special mention.
	Storage stability:	No decomposition when stored and used as directed
	Storage class:	11, Combustible solids
7.3	Specific end uses:	There are no data available.

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Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



	SECTION 8: Exposure	e controls/personal protective equipment	
8.1	Parameters to be monitored Occupational exposure limit values	Does not contain substances with occupational exposure limits.	
	Biological limit values	Does not contain substances with occupational exposure limits.	
8.2	Exposure controls Suitable engineering controls:	Local suction device	
	Individual protective measures, for examp	ple personal protective equipment	
		e wash bottle with pure water. Do not eat, drink or smoke while working.	
		Safety glasses	
	Skin protection Hand protection:	Protective gloves	
	Other:	Wear suitable protective clothing and goggles/face protection when working.	
	Respiratory protection:	Normally no personal respiratory protection necessary.	
		If dust or aerosol is generated, use respiratory protection with recognized filter type	
		Anerkannte industrielle Hygienemaßnahmen beachten. 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.	

9.1	Information on the basic physical and chemical properties		
	Parameter	Value	
	State of aggregation	fixed	
	Colour	colorless	
	Smell	mild, after acetic acid	
	Melting point/freezing point	No data available	
	Boiling point or initial boiling point and boiling range	No data available	
	Flammability	No data available	
	Lower explosion limit upper explosion limit	No data available	
	Flash point	Not applicable	
	Ignition temperature	> 330 °C	
	Decomposition temperature	> 300 °C	
	pH value	No data available	

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

Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



	Kinematic viscosity	No data available
	Solubility	Wsolubility insoluble
	Partition coefficient n-octanol/water (log value)	No data available
	Vapour pressure	No data available
	Density and/or specific gravity	No data available
	Relative vapour density	No data available
	Particle properties	No data available
9.2.	Other information No data available	

	SECTION 10: Stability and reactivity		
10.1	Reactivity	No decomposition when stored and used as directed.	
10.2	Chemical stability	No decomposition when stored and used as directed.	
10.3	Possibility of hazardous reactions	Hazardous reactions: Stable under specified storage conditions. No hazards requiring special mention. Dust may form explosive mixtures with air bilden.	
10.4	Conditions to avoid	No data available	
10.5	Incompatible materials	Strong oxidizing agents	
10.6	Decomposition products	No data available	

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

Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



	SECTION 1	1: Toxicological data		
11.1	Information on hazard classes within the meaning of Regulation (EC) No 1272/2008			
		Not classified according to the available information. Vinyl Acetate - Ethylene Copolymer:		
	acute toxicity	Acute oral toxicity		
		LD50 (rat): > 5,000 mg/kg.		
		Not classified according to the available information. Vinyl Acetate - Ethylene Copolymer:		
	Corrosive/irritant effect on the skin	Acute oral toxicity		
		LD50 (rat): > 5,000 mg/kg.		
		Not classified according to the available information. Vinyl Acetate - Ethylene Copolymer:		
	Serious eye damage/irritation	Acute oral toxicity		
		LD50 (rat): > 5,000 mg/kg.		
		Not classified according to the available information. Vinyl Acetate		
	Sensitisation of the respiratory tract/skin	- Ethylene Copolymer: Acute oral toxicity		
		LD50 (rat): > 5,000 mg/kg.		
		Not classified according to the available information. Vinyl Acetate - Ethylene Copolymer:		
	Germ cell mutagenicity	Acute oral toxicity		
		LD50 (rat): > 5,000 mg/kg.		
		Not classified according to the available information. Vinyl Acetate - Ethylene Copolymer:		
	Carcinogenicity	Acute oral toxicity		
		LD50 (rat): > 5,000 mg/kg.		
		Not classified according to the available information. Vinyl Acetate - Ethylene Copolymer:		
	Reproductive toxicity	Acute oral toxicity		
		LD50 (rat): > 5,000 mg/kg.		
	Specific target organ toxicity at single exposure	Not classified according to the available information. Vinyl Acetate - Ethylene Copolymer: Acute oral toxicity		
	Specific target organ toxicity in case of repeated exposure	LD50 (rat): > 5,000 mg/kg. Not classified according to the available information. Vinyl Acetate - Ethylene Copolymer: Acute oral toxicity		
	Aspiration hazard	LD50 (rat): > 5,000 mg/kg. Not classified according to the available information. Vinyl Acetate - Ethylene Copolymer: Acute oral toxicity LD50 (rat): > 5,000 mg/kg.		

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Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



11.2	Information on other hazards	No data available
11.2.1	Endocrine disrupting properties	The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.
11.2.2	Other information	No data available

	SECTION 12. Environmental information		
12.1	Toxicity	Inhaltsstoffe:	
		Vinylacetat-Ethylen-Copolymer:	
		Toxizität für Fische	
		LC50 (Danio rerio (Zebrabärbling)): > 500 mg/l	
		Expositionszeit: 96 h	
12.2	Persistence and degradability	No data available	
12.3	Bioaccumulative potential	No data available	
12.4	Mobility in soil	No data available	
12.5	Results of the PBT and vPvB assessment	This substance/mixture does not contain components at concentrations of 0.1% or higher that are classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).	
12.6	Endocrine disrupting properties	The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.	
12.7	Other adverse effects	No data available	

SECTION 13: Disposal instructions		
13.1	Waste treatment process	
	General information	Dispose of in compliance with local official regulations.
	Disposal methods	Deliver empty containers to an approved waste disposal facility for recovery or disposal.

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Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



	SECTION 14: Transport information		
14.1	ADR	Not classified as dangerous goods.	
14.2	ADN	Not classified as dangerous goods.	
14.3	RID	Not classified as dangerous goods.	
14.4	IMDG	Not classified as dangerous goods.	
14.5	IATA	Not classified as dangerous goods.	
14.6	Special precautions for the user:	Not classified as dangerous goods.	
14.7	Carriage in bulk in accordance with Annex II of the MARPOL Convention and the IBC Code:	Not applicable to product as delivered.	

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:	Not applicable	
	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		

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Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



	Water hazard class	not hazardous to water (nwg)	
	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	Not applicable	
15.2	Chemical safety assessment	No data available	

	SECTION 16: Other information			
16.1	Information on the revision	Not relevant.		
	Important literature references and data sources:	Full text of H-phrases		
		Full text of other abbreviations		
		ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for Materials Testing; bw - body weight; CLP - Regulation on Classification, Labelling and Packaging of Substances, Regulation (EC) No 1272/2008; CMR - Carcinogenic, Mutagenic or Reproductive toxicant; DIN - German Institute for Standardization standard; DSL - List of Domestic Substances (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x % reaction; ELx - Loading rate associated with x % reaction; EMS - Emergency Response Plan; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x % growth rate; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk; IC50 - Half Maximum Inhibitory Concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Chemical Substances Existing in China; IMDG - International Maritime Dangerous Goods Code; IMO - International Maritime Organization; ISHL - Occupational Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Inventory of Chemicals Existing in Korea; LC50 - Lethal Concentration for 90% of a Test Population; LD50 - Lethal Dose for 50% of a Test Population (Mean Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n. o.s Not elsewhere specified; NO(A)EC - Concentration at which no (adverse) effect is apparent; NO(A)EL - Dose at which no (adverse) effect is apparent; Population for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention (OSCPP); PBT		
		1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RID - Regulation concerning the International Carriage of Dangerous Goods by Rail;		

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

Friedensstifter® KL II / Stufe 1 Article no.: No. 90984

Revised on: 15.05.2023



Training information:	Substances; TSCA - Toxic Substances Control Act (United States); UN - Unite Nations; vPvB - Very Persistent and Very Bioaccumulative 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 intend 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 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 otherwi