

EU - Safety data sheet

according to UK REACH Regulation

Revision date: 12.04.2024

Revision No: 1,06 - Replaces version: 1,05

SilaPress Vario Powder

SILADENT

Date of printing: 09.01.2025

Page: 1 / 7

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1 Product identifier**
Commercial product name: SilaPress Vario Powder
Product group: Powder component
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Use of the substance/mixture: Manufacture of dental products.
- 1.3 Details of the supplier of the safety data sheet**
Manufacturer: rettec® Kunststofftechnik GmbH
Street / mailbox: Industriestraße 2
Country code. / postal code / city: D-61191 Rosbach v.d.H
Phone: +49 (0) 6007 - 9157 0
Fax: +49 (0) 6007 - 9157 29
E-mail: info@rettec-dent.de
Contact person: Research & Development
Department
E-mail: info@rettec-dent.de
Website: www.retec-dent.de
Supplier: SILADENT Dr. Böhme & Schöps GmbH
Street / mailbox: Im Klei 26
Country code. / postal code / city: D - 38644 Goslar
Phone: 0 53 21 / 37 79 – 0
Fax: 0 53 21 / 38 96 32
E-mail / Website: info@siladent.de / www.siladent.de
- 1.4 Emergency telephone number:** +49 (0) 6007-91570

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture:**
GB CLP Regulation: Aquatic Chronic 3; H412
Full text of hazard statements: see SECTION 16.
- 2.2 Label elements:**
GB CLP Regulation
Hazard statements:
H412 Harmful to aquatic life with long lasting effects.
Precautionary statements:
P273 Avoid release to the environment.
P501 Dispose of contents/container to as hazardous waste - in accordance with local and national legislation - suitable, approved incinerator for combustible organic waste.
Special labelling of certain mixtures:
EUH208 Contains dibenzoyl peroxide; benzoyl peroxide. May produce an allergic reaction.

SECTION 3: Composition/information on ingredients

- 3.2 Mixtures**
Chemical characterisation: Mixture based on polymethyl methacrylates and catalyst.

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
9011-14-7	Acrylic polymer			95 - <= 100 %

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SilaPress Vario Powder

SILADENT

Date of printing: 09.01.2025

Page: 2 / 7

94-36-0	dibenzoyl peroxide; benzoyl peroxide		< 1 %
	202-327-6	01-2119511472-50	
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1; H241 H319 H317 H400 H410		

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1	Description of first aid measures:	
	General information:	Get medical advice/attention if you feel unwell.
	After inhalation:	Provide fresh air.
	After contact with skin:	Wash with plenty of water. Take off contaminated clothing and wash it before reuse.
	After contact with eyes:	Rinse immediately carefully and thoroughly with eye-bath or water.
	After ingestion:	Rinse mouth immediately and drink plenty of water.
4.2	Most important symptoms and effects, both acute and delayed:	No information available.
4.3	Indication of any immediate medical attention and special treatment needed:	Treat symptomatically.

SECTION 5: Firefighting measures

5.1	Extinguishing media:	
	Suitable extinguishing media:	Foam Extinguishing powder Carbon dioxide (CO2).
	Unsuitable extinguishing media:	Full water jet.
5.2	Special hazards arising from the substance or mixture:	In case of fire may be liberated: Carbon monoxide, Carbon dioxide
5.3	Advice for firefighters:	In case of fire: Wear self-contained breathing apparatus.
	Additional information:	Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures:	
	General measures	Avoid dust formation. Do not breathe dust.
6.2	Environmental precautions:	Do not allow to enter into surface water or drains.
6.3	Methods and material for containment and cleaning up:	Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.
6.4	Reference to other sections:	Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

SECTION 7: Handling and storage

7.1	Precautions for safe handling:	
	Advice on safe handling:	No special measures are necessary.

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Revision date: 12.04.2024

Revision No: 1,06 - Replaces version: 1,05

SilaPress Vario Powder

SILADENT

Date of printing: 09.01.2025

Page: 3 / 7

Advice on protection against fire and explosion:

No special fire protection measures are necessary.

Advice on general occupational hygiene:

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels:

Keep container tightly closed.

Hints on joint storage

No special measures are necessary.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL

8.2 Exposure controls:

Individual protection measures, such as personal protective equipment

Eye/face protection:

Wear eye/face protection.

Hand protection:

Material: Protective gloves against mechanical risks according to EN 388. Additional information: Protective gloves should be changed regularly, especially after intensive contact with the product. Gloves must be removed and replaced if they show signs of wear and tear or chemical breakthroughs. A suitable type of glove must be selected for each workplace. Please note the information provided by the glove supplier with regard to permeability and breakthrough time. Also, take into account the specific, local conditions under which the product is used, such as the risk of cuts, abrasion and contact time.

Skin protection:

Wear suitable protective clothing.

Respiratory protection:

In case of inadequate ventilation, wear respiratory protection. A suitable dust mask or respirator with filter type P1 or FFP1 (EN143 or EN149) may be suitable. In the unlikely event that particularly large amounts of dust are formed, a self-contained breathing apparatus may be appropriate.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	Powder
Colour:	see packing
Odour:	characteristic
Melting point/freezing point:	ca. 110 °C
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	not determined not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	> 250 °C
Auto-ignition temperature:	> 400 °C
Decomposition temperature:	not determined
pH-Value:	not determined
Water solubility:	The study does not need to be conducted because the substance is known to be

EU - Safety data sheet

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SilaPress Vario Powder

SILADENT

Date of printing: 09.01.2025

Page: 4 / 7

Solubility in other solvents:
Partition coefficient n-octanol/water:
Vapour pressure:
Density (at 20 °C):
Bulk density (at 20 °C):
Relative vapour density:

insoluble in water.
Soluble in hydrocarbons.
not determined
not determined
1,16 g/cm³
700 - 750 kg/m³
not determined

9.2 Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid:

not determined

Gas:

not applicable

Oxidizing properties:

Not oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

100 %

SECTION 10: Stability and reactivity

10.1	Reactivity:	No hazardous reaction when handled and stored according to provisions.
10.2	Chemical stability:	The product is stable under storage at normal ambient temperatures.
10.3	Possibility of hazardous reactions:	No known hazardous reactions.
10.4	Conditions to avoid:	None.
10.5	Incompatible materials:	No information available.
10.6	Hazardous decomposition products	Exothermal decomposition with formation of: Methyl methacrylate.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicokinetics, metabolism and distribution: Toxicological data are not available.

Acute toxicity:

Based on available data, the classification criteria are not met.

ATEmix calculated:

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity:

Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Sensitising effects:

Based on available data, the classification criteria are not met.
Contains dibenzoyl peroxide; benzoyl peroxide. May produce an allergic reaction.

Carcinogenic/mutagenic/toxic effects for reproduction:

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Revision No: 1,06 - Replaces version: 1,05

SilaPress Vario Powder

SILADENT

Date of printing: 09.01.2025

Page: 5 / 7

Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard:	Based on available data, the classification criteria are not met.
Additional information on tests:	The mixture is classified as not hazardous according to Directive 1999/45/EC.

SECTION 12: Ecological information

12.1	Toxicity	The product is not: Ecotoxic.
12.2	Persistence and degradability:	The product has not been tested.
12.3	Bioaccumulative potential:	The product has not been tested.
12.4	Mobility in soil:	The product has not been tested.
12.5	Results of PBT and vPvB assessment:	The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH. The product has not been tested.
12.6	Endocrine disrupting properties:	This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.
12.7	Other adverse effects:	No information available.
	Further information:	Avoid release to the environment.

SECTION 13: Disposal considerations

13.1	Waste treatment methods:	
	Disposal recommendations:	Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.
	Contaminated packaging:	Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

	<u>Land transport (ADR/RID):</u>	
14.1	UN number:	No dangerous good in sense of this transport regulation.
14.2	UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3	Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4	Packing group:	No dangerous good in sense of this transport regulation.
	<u>Inland waterways transport (ADN)</u>	
14.1	UN number:	No dangerous good in sense of this transport regulation.
14.2	UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3	Transport hazard class(es):	No dangerous good in sense of this transport regulation.

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SilaPress Vario Powder

SILADENT

Date of printing: 09.01.2025

Page: 6 / 7

14.4	Packing group:	No dangerous good in sense of this transport regulation.
	<u>Marine transport (IMDG)</u>	
14.1	UN number:	No dangerous good in sense of this transport regulation.
14.2	UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3	Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4	Packing group:	No dangerous good in sense of this transport regulation.
	<u>Air transport (ICAO-TI/IATA-DGR)</u>	
14.1	UN number:	No dangerous good in sense of this transport regulation.
14.2	UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3	Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4	Packing group:	No dangerous good in sense of this transport regulation.
14.5	Environmental hazards ENVIRONMENTALLY HAZARDOUS:	No
14.6	Special precautions for user	No information available.
14.7	Maritime transport in bulk according to IMO instruments:	not applicable

SECTION 15: Regulatory information

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture EU regulatory information Information according to 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)
	Additional information:	To follow: 850/2004/EC , 79/117/EEC , 689/2008/EC
	National regulatory information Employment restrictions:	Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.
	Water contaminating class (D):	1 - slightly hazardous to water
15.2	Chemical safety assessment	Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

16.1	Abbreviations and acronyms	
	Org. Perox	Organic peroxide
	Eye Irrit:	Eye irritation
	Skin Sens:	Skin sensitisation
	Aquatic Acute:	Acute aquatic hazard
	Aquatic Chronic:	Chronic aquatic hazard
	ADR:	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
	IMDG:	International Maritime Code for Dangerous Goods
	IATA:	International Air Transport Association
	GHS:	Globally Harmonized System of Classification and Labelling of Chemicals
	EINECS:	European Inventory of Existing Commercial Chemical Substances
	ELINCS:	European List of Notified Chemical Substances
	CAS	Chemical Abstracts Service
	LC50:	Lethal concentration, 50%
	LD50:	Lethal dose, 50%

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SILADENT

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Page: 7 / 7

Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text):

- H241 Heating may cause a fire or explosion.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.
EUH208 Contains dibenzoyl peroxide; benzoyl peroxide. May produce an allergic reaction.

Further Information:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)