

Safety Data Sheet

according to UK REACH Regulation

VSXE® One

Revision date: 31.07.2023

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

1.1. Product identifier

VSXE® One

Further trade names

VSXE® One

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Hydrophilic, medium viscosity, addition-curing, elastomeric precision impression material based on vinylsiloxane-ether® -base.

Medical device for use in dentistry, observe instructions for use.

1.3. Details of the supplier of the safety data sheet

Company name:	Kettenbach GmbH & Co. KG	
Street:	Im Heerfeld 7	
Place:	D-35713 Eschenburg	
Telephone:	+ 49(0) 2774/705-0	Telefax: +49 (0)2774/705-66
E-mail:	info@kettenbach.com	
Internet:	www.kettenbach.com	
Responsible Department:	R&D	

Further Information

The product is intended for professional use.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

Safety Information Sheet for Medical Devices The particulars given in the Safety Information Sheet only apply to the described product in connection with its appropriate utilization. These particulars are based on the latest state of our knowledge and information. They serve the purpose of describing our product under the aspect of hazards caused by such product and pertaining safety actions. They do not constitute any guarantee of product quality and/or quality features. The particulars given in this Safety Information Sheet are not required according to the Article 31 and Annex II of Regulation (EC) No 1907/2006 (REACH Regulation). This product is classified as a medical device. Medical devices are exempt from the labelling provisions. They merely serve the purpose of providing sufficient information on the voluntary basis with a view to ensure the safe utilization of such substance/mixture/product.

2.2. Label elements

Additional advice on labelling

The product is not:

2.3. Other hazards

No risks worthy of mention.

Due to the physical form (paste), classification with H372 and H373 is not indicated. Inhalation is not possible.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Preparation of polyether- and silicone polymers, fillers, colorants and surfactants with platinum- catalyst (ppm-range).

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
68855-54-9	Flux calcined diatomaceous earth			20-40 %
	272-489-0		01-2119488518-22	
	STOT RE 2; H373			
14464-46-1	Cristobalite			<= 10 %
	238-455-4			
	STOT RE 1; H372			
NAP	Polydimethylsiloxane with functional groups			1 - < 5 %
	Aquatic Chronic 3; H412			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
68855-54-9	272-489-0	Flux calcined diatomaceous earth	20-40 %
		inhalation: LC50 = >2.6 mg/l (dusts or mists); dermal: Data lacking; oral: LD50 = >2000 mg/kg	
14464-46-1	238-455-4	Cristobalite	<= 10 %
		inhalation: Data lacking (gases); dermal: Data lacking; oral: Data lacking	
NAP		Polydimethylsiloxane with functional groups	1 - < 5 %
		inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

not applicable

After contact with skin

In general the product is not skin irritative.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Seek medical attention if problems persist.

4.2. Most important symptoms and effects, both acute and delayed

No data available

4.3. Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Atomized water.
alcohol resistant foam.
Carbon dioxide (CO2).

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Unsuitable extinguishing media

None known.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to the escape of irritating gases and vapours.

Formaldehyde, Silicon dioxide (SiO₂), Carbon dioxide (CO₂)

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

Other information

Allow stiffening. Take up mechanically.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

SECTION 12: Ecological information

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear personal protection equipment (refer to section 8).

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Avoid contact with skin, eyes and clothes.

When using do not eat, drink, smoke, sniff.

Further information on handling

Keep locked up and out of reach of children.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special requirements.

Hints on joint storage

Keep away from food and drink.

Further information on storage conditions

Please pay attention to the information on the package!

7.3. Specific end use(s)

Not required.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
13463-67-7	Titanium dioxide, respirable	-	4		TWA (8 h)	WEL

8.2. Exposure controls

Appropriate engineering controls

not applicable

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Single-use gloves.

Suitable material: PE (polyethylene).

Unsuitable material: NR (Natural rubber (Caoutchouc), Natural latex).

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Not required.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Paste
Colour:	Catalyst: grey-white. Base: violet.
Odour:	odourless

Test method

Melting point/freezing point:	not applicable
Boiling point or initial boiling point and boiling range:	No data available
Flammability:	not applicable
Lower explosion limits:	not applicable
Upper explosion limits:	not applicable
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH-Value:	No data available
Viscosity / kinematic:	No data available
Water solubility:	insoluble OECD 105
Dissolution rate:	No data available
Partition coefficient n-octanol/water:	No data available
Density (at 20 °C):	ca. 1,3 g/cm ³

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

Not applicable.

Oxidizing properties

Not applicable.

Further Information

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The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: Stability and reactivity

10.1. Reactivity

None by intended use.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Storage outside of the predetermined storage conditions (see packaging)

10.5. Incompatible materials

None by intended use.

strong base

Oxidising agent, strong

10.6. Hazardous decomposition products

Formaldehyde

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

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

Acute toxicity, oral LD50: > 2000 mg/kg Rat

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

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
68855-54-9	Flux calcined diatomaceous earth				
	oral	LD50 >2000 mg/kg	Rat		
	dermal	Data lacking			
	inhalation (4 h) dust/mist	LC50 >2.6 mg/l	Rat		
14464-46-1	Cristobalite				
	oral	Data lacking			
	dermal	Data lacking			
	inhalation	Data lacking			
NAP	Polydimethylsiloxane with functional groups				
	oral	LD50 >2000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
	inhalation	Data lacking			

Irritation and corrosivity

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

Irritant effect on the skin: non-irritant.

Irritant effect on the eye: non-irritant.

Sensitising effects

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

no danger of sensitization.

Carcinogenic/mutagenic/toxic effects for reproduction

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.

11.2. Information on other hazards

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Other information

None by intended use.

SECTION 12: Ecological information

12.1. Toxicity

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

product has not been tested.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
14464-46-1	Cristobalite					
	Aquatic toxicity	Data lacking				
NAP	Polydimethylsiloxane with functional groups					
	Acute fish toxicity	LC50 >100 mg/l	96 h	zebra fish		
	Acute algae toxicity	ErC50 >100 mg/l	72 h	Pseudokirchneriella subcapitata		

12.2. Persistence and degradability

product has not been tested.

12.3. Bioaccumulative potential

product has not been tested.

12.4. Mobility in soil

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.

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

None known.

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Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not remove with domestic waste.

List of Wastes Code - residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing hazardous substances; hazardous waste

List of Wastes Code - used product

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

List of Wastes Code - contaminated packaging

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

Contaminated packaging

Non-contaminated packages may be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

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

Inland waterways transport (ADN)

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

Marine transport (IMDG)

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

Air transport (ICAO-TI/IATA-DGR)

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

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS:	No
Danger releasing substance:	not applicable

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14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

not applicable

Other applicable information

No dangerous good in sense of these transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

National regulatory information

Water hazard 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

Changes

Date of preparation / Revised on: 31/07/2023

Version number: 1,01

Replaces version number: 1,00 (01/06/2023)

Abbreviations and acronyms

ATE: Acute toxicity estimate. CAS: Chemical abstracts service. CFR: Code of Federal Regulations. DNEL: Derived No Effect Level EC50: 50% of maximal effective concentration. FDA: Food and Drug Administration. GHS: Globally Harmonised System. IATA: International air transport association. ICAO: Technical instructions for the safe transport of dangerous goods by air. IMDG: International maritime dangerous goods. LC50: Lethal concentration to 50 % of a test population. LD50: Lethal dose to 50% of a test population (median lethal dose). NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PEL: Permissible Exposure Limit. PNEC: Predicted No Effect Concentration. REL: Recommended exposure limit. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. TWA: 8-hour Time Weighted Averages (long-term exposure limit). US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

Relevant H and EUH statements (number and full text)

H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful to aquatic life with long lasting effects.

Further Information

Classification Titanium dioxide (in powder form): Based on the measurements available for this product on the proportion of particles with an aerodynamic diameter smaller than 10 µm in the dust, it does not meet the requirements for classification according to Regulation 2020/217 (14th ATP to Regulation (EU) 1272/2008, Annex VI).

Training instructions: Use only by personnel trained in dentistry.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

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