

Safety Data Sheet

according to UK REACH Regulation

Panasil contact plus

Revision date: 03.04.2024

Page 1 of 7

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

1.1. Product identifier

Panasil contact plus

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

Use of the substance/mixture

Low viscosity, addition-curing, elastomeric precision impression material based on polyvinyl siloxane. 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	

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

There is no requirement for the product to be specially labelled according to EC directives or the corresponding national laws.

2.3. Other hazards

No risks worthy of mention.

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Preparation of silicone polymers and fillers with platinum-catalyst (ppm-range).

Safety Data Sheet

according to UK REACH Regulation

Panasil contact plus

Revision date: 03.04.2024

Page 2 of 7

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
14464-46-1	Cristobalite			40 - <50 %
	238-455-4			
	STOT RE 1; H372			

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		
14464-46-1	238-455-4	Cristobalite	40 - <50 %
	inhalation: Data lacking (gases); dermal: Data lacking; oral: Data lacking		

SECTION 4: First aid measures

4.1. Description of first aid measures

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. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Seek medical attention if problems persist.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water fog. Foam. Carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture

Not applicable.

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

Not required.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Take up mechanically.

6.4. Reference to other sections

No release of hazardous substances.

Safety Data Sheet

according to UK REACH Regulation

Panasil contact plus

Revision date: 03.04.2024

Page 3 of 7

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No special precautionary measures are necessary.

Advice on protection against fire and explosion

No special precautionary measures are necessary.

Advice on general occupational hygiene

The usual precautions when handling chemicals have to be obtained.

Avoid contact with skin, eyes and clothes.

Further information on handling

No special precautionary measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special requirements.

Hints on joint storage

Not required.

Further information on storage conditions

No special requirements.

7.3. Specific end use(s)

Not required.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls

Appropriate engineering controls

not applicable

Individual protection measures, such as personal protective equipment

Eye/face protection

Not required.

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: blue. Base: violet.

Safety Data Sheet

according to UK REACH Regulation

Panasil contact plus

Revision date: 03.04.2024

Page 4 of 7

Odour:	odourless	
Melting point/freezing point:		not applicable
Boiling point or initial boiling point and boiling range:		not applicable
pH-Value:		neutral
Water solubility:		insoluble
Density (at 20 °C):		1,2 - 1,4 g/cm ³

9.2. Other information

Information with regard to physical hazard classes

Explosive properties
not Explosive.

SECTION 10: Stability and reactivity

10.1. Reactivity

None by intended use.

10.2. Chemical stability

None by intended use.

10.3. Possibility of hazardous reactions

None by intended use.

10.4. Conditions to avoid

None by intended use.

10.5. Incompatible materials

None by intended use.

10.6. Hazardous decomposition products

None by intended use.

Further information

Please pay attention to the Directions for Use.

SECTION 11: Toxicological information

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

Acute toxicity

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
14464-46-1	Cristobalite				
	oral	Data lacking			
	dermal	Data lacking			
	inhalation	Data lacking			

Irritation and corrosivity

Irritant effect on the skin: non-irritant.
Irritant effect on the eye: non-irritant.

Sensitising effects

no danger of sensitization.

Safety Data Sheet

according to UK REACH Regulation

Panasil contact plus

Revision date: 03.04.2024

Page 5 of 7

11.2. Information on other hazards

Other information

None by intended use.

SECTION 12: Ecological information

12.1. Toxicity

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				

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.

Further information

Do not allow to enter into surface water or drains.

1 (slightly hazardous to water)

Doesn't get into the sewage water as long as the process is carried out according to regulations.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Remove according to the regulations.

List of Wastes Code - residues/unused products

070217 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; waste containing silicones other than those mentioned in 07 02 16

List of Wastes Code - used product

200399 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; municipal wastes not otherwise specified

Contaminated packaging

Completely emptied packings can be re-cycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID 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.

Safety Data Sheet

according to UK REACH Regulation

Panasil contact plus

Revision date: 03.04.2024

Page 6 of 7

Inland waterways transport (ADN)

14.1. UN number or ID 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.

Marine transport (IMDG)

14.1. UN number or ID 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.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID 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

N/A

14.7. Maritime transport in bulk according to IMO instruments

N/A

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

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

For this substance a chemical safety assessment is not required.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 2,14,16.

Date of preparation / Revised on: 03/04/2024

Version number: 3,05

Replaces version number: 3,04 (14/09/2024)

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.

Safety Data Sheet

according to UK REACH Regulation

Panasil contact plus

Revision date: 03.04.2024

Page 7 of 7

Relevant H and EUH statements (number and full text)

H372 Causes damage to organs through prolonged or repeated exposure.

Further Information

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.

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