

## Safety Data Sheet

according to UK REACH Regulation

### Panasil monophase Medium

Revision date: 21.09.2022

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

##### 1.1. Product identifier

Panasil monophase Medium

##### **Further trade names**

Panasil monophase

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

##### **Use of the substance/mixture**

Medium viscosity, addition-curing, elastomeric monophase 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.

##### 2.2. Label elements

##### **GB CLP Regulation**

##### **Precautionary statements**

P501	Dispose of contents/container to	Dispose of contents/container in accordance with local/regional/national international regulations..
P305+P354+P338	IF IN EYES:	Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P280	Wear protective gloves.	

##### **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.

#### SECTION 3: Composition/information on ingredients

##### 3.2. Mixtures

##### **Chemical characterization**

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

##### **Hazardous components**

none (according to UK REACH Regulation)

#### SECTION 4: First aid measures

##### 4.1. Description of first aid measures

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#### General information

Symptoms: No known symptoms to date.

#### 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 (CO<sub>2</sub>).

#### 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.

### 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.

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#### 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

##### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
56-81-5	Glycerol, mist	-	10		TWA (8 h)	WEL

#### 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.

##### Environmental exposure controls

Not required.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state:	Paste	
Colour:	Catalyst: white. Base: blue.	
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
Vapour pressure:		not applicable
Density (at 20 °C):		ca. 1,5 g/cm <sup>3</sup>

#### 9.2. Other information

##### Information with regard to physical hazard classes

Explosive properties

not Explosive.

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#### 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

###### **Irritation and corrosivity**

Irritant effect on the skin: non-irritant.

Irritant effect on the eye: non-irritant.

###### **Sensitising effects**

no danger of sensitization.

##### 11.2. Information on other hazards

###### **Other information**

None by intended use.

#### SECTION 12: Ecological information

##### 12.1. Toxicity

product has not been tested.

##### 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.

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#### 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:** N/A

**14.2. UN proper shipping name:** N/A

**14.3. Transport hazard class(es):** N/A

**14.4. Packing group:** N/A

#### Inland waterways transport (ADN)

**14.1. UN number or ID number:** N/A

**14.2. UN proper shipping name:** N/A

**14.3. Transport hazard class(es):** N/A

**14.4. Packing group:** N/A

#### Marine transport (IMDG)

**14.1. UN number or ID number:** N/A

**14.2. UN proper shipping name:** N/A

**14.3. Transport hazard class(es):** N/A

**14.4. Packing group:** N/A

Segregation group: 4 - chlorates

#### Air transport (ICAO-TI/IATA-DGR)

**14.1. UN number or ID number:** N/A

**14.2. UN proper shipping name:** N/A

**14.3. Transport hazard class(es):** N/A

**14.4. Packing group:** N/A

Danger releasing substance: N/A

#### 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.

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#### 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

Update 2022-09-21

##### Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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