

# Safety Data Sheet

according to UK REACH Regulation

## Panasil Adhesive

Revision date: 26.02.2024

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

#### 1.1. Product identifier

Panasil Adhesive

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

##### Use of the substance/mixture

Adhesive for Kettenbach addition-curing impression material and reline impression materials.  
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

Flam. Liq. 2; H225  
Skin Irrit. 2; H315  
Eye Dam. 1; H318  
STOT SE 3; H336

Full text of hazard statements: see SECTION 16.

\*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

##### GB CLP Regulation

##### Hazard components for labelling

ethyl acetate  
Tetrabutyl orthotitanate

Signal word: Danger

Pictograms:



##### Hazard statements

H225 Highly flammable liquid and vapour.

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H315	Causes skin irritation.
H318	Causes serious eye damage.
H336	May cause drowsiness or dizziness.

#### Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280	Wear protective gloves/protective clothing and eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P370+P378	In case of fire: Use sand, extinguishing powder or alcohol-resistant foam to extinguish.
P403+P235	Store in a well-ventilated place. Keep cool.

#### 2.3. Other hazards

Formation of potentially explosive vapor/air mixtures is possible.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Chemical characterization

Preparation based on silicone resin in organic solvents.

##### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
141-78-6	ethyl acetate			20 - <30 %
	205-500-4	607-022-00-5		
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336 EUH066			
1330-20-7	xylene			5 - <10 %
	215-535-7	601-022-00-9		
	Flam. Liq. 3, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2; H226 H332 H312 H315			
5593-70-4	Tetrabutyl orthotitanate			1 - <5 %
	227-006-8		01-2119967423-33	
	Flam. Liq. 3, Skin Irrit. 2, Eye Dam. 1, STOT SE 3, STOT SE 3; H226 H315 H318 H335 H336			
100-41-4	ethylbenzene			1 - <5 %
	202-849-4	601-023-00-4		
	Flam. Liq. 2, Acute Tox. 4, STOT RE 2, Asp. Tox. 1; H225 H332 H373 H304			

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		
1330-20-7	215-535-7	xylene	5 - <10 %
	inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); dermal: ATE = 1100 mg/kg		
5593-70-4	227-006-8	Tetrabutyl orthotitanate	1 - <5 %
	inhalation: LC50 = 20 mg/l (vapours); dermal: LD50 = 5300 mg/kg; oral: LD50 = 2000 mg/kg		
100-41-4	202-849-4	ethylbenzene	1 - <5 %
	inhalation: LC50 = 17,2 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); dermal: LD50 = 15400 mg/kg; oral: LD50 = 3500 mg/kg		

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#### 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

Provide fresh air.

###### After contact with skin

After contact with skin, wash immediately with plenty of water and soap.

###### After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

###### After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

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

Symptoms may be delayed. Narcotic effect. Vapor concentrations above recommended exposure levels are irritating to the eyes and the respiratory tract, may cause headaches and dizziness, are anesthetic and may have other severe central nervous system effects. Drowsiness, dizziness, disorientation, vertigo.

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

Wash off promptly and flush contaminated skin with water. Promptly remove clothing if soaked through and flush skin with water. If swallowed, do NOT induce vomiting. Give a glass of water. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses.

#### SECTION 5: Firefighting measures

##### 5.1. Extinguishing media

###### Suitable extinguishing media

All standard extinguishing agents are suitable.

###### Unsuitable extinguishing media

Avoid water in straight hose stream; will scatter and spread fire.

##### 5.2. Special hazards arising from the substance or mixture

Vapours may form explosive mixtures with air.

##### 5.3. Advice for firefighters

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

Do not allow to enter into surface water or drains.

#### SECTION 6: Accidental release measures

##### 6.1. Personal precautions, protective equipment and emergency procedures

###### General advice

Remove all sources of ignition.

Wear 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

###### Other information

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

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### 6.4. Reference to other sections

No release of hazardous substances.  
Personal protection equipment: see section 8

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Advice on safe handling

Keep away from sources of ignition - No smoking.  
Wear personal protection equipment (refer to section 8).

#### Advice on protection against fire and explosion

Take precautionary measures against static discharges.

#### Advice on general occupational hygiene

Avoid contact with skin, eyes and clothes. Change contaminated clothing.  
Wash hands before breaks and after work.  
Protect skin by using skin protective cream.  
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

Keep container tightly closed and store in a cool place.  
Store only in original container.

#### Hints on joint storage

Keep away from food and drink.

#### Further information on storage conditions

Protect against: heat.

### 7.3. Specific end use(s)

Not applicable.

## 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
141-78-6	Ethyl acetate	200	734		TWA (8 h)	WEL
		400	1468		STEL (15 min)	WEL
100-41-4	Ethylbenzene	100	441		TWA (8 h)	WEL
		125	552		STEL (15 min)	WEL
1330-20-7	Xylene: mixed isomers	50	220		TWA (8 h)	WEL
		100	441		STEL (15 min)	WEL

#### Biological Monitoring Guidance Values (EH40)

CAS No	Substance	Parameter	Value	Test material	Sampling time
1330-20-7	Xylene, o-, m-, p- or mixed isomers	methyl hippuric acid (creatinine)	650 mmol/mol	urine	Post shift

### 8.2. Exposure controls

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#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Safety glasses.

##### Hand protection

Disposable gloves

Hand protection: Suitable material: Butyl caoutchouc (butyl rubber)

Wash hands before breaks and after work.

Protect skin by using skin protective cream.

##### Skin protection

Protective clothing.

Avoid contact with skin, eyes and clothes.

Take off contaminated clothing and wash it before reuse.

##### Respiratory protection

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

Provide adequate ventilation.

##### Environmental exposure controls

Do not allow to enter into surface water or drains.

## SECTION 9: Physical and chemical properties

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

Physical state:	Liquid
Colour:	blue
Odour:	Aromatic
Odour threshold:	No data available
Melting point/freezing point:	<-60 °C
Boiling point or initial boiling point and boiling range:	>70 °C
Flammability:	No data available
Lower explosion limits:	2,1 vol. %
Upper explosion limits:	11,5 vol. %
Flash point:	3 °C
Auto-ignition temperature:	> 400 °C
Decomposition temperature:	No data available
pH-Value:	No data available
Viscosity / kinematic:	No data available
Water solubility: (at 20 °C)	practically insoluble
Solubility in other solvents No data available	
Dissolution rate:	No data available
Partition coefficient n-octanol/water:	No data available
Dispersion stability:	not applicable
Vapour pressure: (at 20 °C)	< 102 hPa
Density (at 20 °C):	<1,1 g/cm <sup>3</sup>
Relative density:	No data available
Bulk density:	not applicable
Relative vapour density:	No data available
Particle characteristics:	not applicable

### 9.2. Other information

#### Information with regard to physical hazard classes

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#### Explosive properties

Formation of potentially explosive vapor/air mixtures is possible.

#### Sustaining combustion:

No data available

#### Self-ignition temperature

Solid:

not applicable

Gas:

not applicable

#### Oxidizing properties

not applicable

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Vapours can form explosive mixtures with air.

### 10.2. Chemical stability

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

### 10.3. Possibility of hazardous reactions

None by intended use.

### 10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames.

### 10.5. Incompatible materials

None by intended use.

Oxidizing agent

### 10.6. Hazardous decomposition products

Formaldehyde

#### Further information

Heating may cause a fire.

## 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.

Irritant effect on the skin: non-irritant.

Irritant effect on the eye: irritant.

Respiratory or skin sensitisation: no danger of sensitization.

#### ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) 11000 mg/kg; ATE (inhalation vapour) 58,83 mg/l; ATE (inhalation dust/mist) 10,00 mg/l

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
1330-20-7	xylene				
	dermal	ATE 1100 mg/kg			
	inhalation vapour	ATE 11 mg/l			
	inhalation dust/mist	ATE 1,5 mg/l			
5593-70-4	Tetrabutyl orthotitanate				
	oral	LD50 2000 mg/kg	Rat		
	dermal	LD50 5300 mg/kg			
	inhalation vapour	LC50 20 mg/l			
100-41-4	ethylbenzene				
	oral	LD50 3500 mg/kg	Rat	GESTIS	
	dermal	LD50 15400 mg/kg	Rabbit	GESTIS	
	inhalation (4 h) vapour	LC50 17,2 mg/l	Rat		
	inhalation dust/mist	ATE 1,5 mg/l			

#### Irritation and corrosivity

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/eye irritation: Causes serious eye damage.

#### Sensitising effects

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

#### Carcinogenic/mutagenic/toxic effects for reproduction

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

May cause drowsiness or dizziness. (ethyl acetate)

#### 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

Preparation not tested. No data available.

#### 11.2. Information on other hazards

##### Further information

Harmful by inhalation and if swallowed.

Hazards identification: Nausea. Headache. Vapours may cause drowsiness and dizziness.

After skin contact: Has de-greasing effect on the skin.

Following eye contact: Irritant.

Harmful: may cause lung damage if swallowed.

### SECTION 12: Ecological information

#### 12.1. Toxicity

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

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
5593-70-4	Tetrabutyl orthotitanate					
	Acute fish toxicity	LC50 mg/l	1740	96 h		
	Acute crustacea toxicity	EC50	590 mg/l	48 h		
	Fish toxicity	NOEC mg/l	4-20	21 d		
100-41-4	ethylbenzene					
	Acute fish toxicity	LC50	4,2 mg/l	96 h	Oncorhynchus mykiss	ECHA
	Acute algae toxicity	ErC50	3,6 mg/l	96 h	Pseudokirchneriella subcapitata	ECHA

### 12.3. Bioaccumulative potential

#### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
100-41-4	ethylbenzene	3,15

### 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

Leakage into the environment must be prevented.

## 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

Cleaned containers may be recycled.

## SECTION 14: Transport information



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#### Land transport (ADR/RID)

**14.1. UN number or ID number:** UN 1866  
**14.2. UN proper shipping name:** RESIN SOLUTION  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** II  
 Hazard label: 3



Classification code: F1  
 Special Provisions: 640D  
 Limited quantity: 5 L  
 Excepted quantity: E2  
 Transport category: 2  
 Hazard No: 33  
 Tunnel restriction code: D/E

#### Inland waterways transport (ADN)

**14.1. UN number or ID number:** UN 1866  
**14.2. UN proper shipping name:** Resin solution  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** II  
 Hazard label: 3



Classification code: F1  
 Special Provisions: 640D  
 Limited quantity: 5 L  
 Excepted quantity: E2

#### Marine transport (IMDG)

**14.1. UN number or ID number:** UN 1866  
**14.2. UN proper shipping name:** RESIN SOLUTION  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** II  
 Hazard label: 3



Special Provisions: -  
 Limited quantity: 5 L  
 Excepted quantity: E2  
 EmS: F-E, S-E

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

**14.1. UN number or ID number:** UN 1866  
**14.2. UN proper shipping name:** RESIN SOLUTION  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** II  
 Hazard label: 3

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Special Provisions:	A3	
Limited quantity Passenger:	1 L	
Passenger LQ:	Y341	
Excepted quantity:	E2	
IATA-packing instructions - Passenger:		353
IATA-max. quantity - Passenger:		5 L
IATA-packing instructions - Cargo:		364
IATA-max. quantity - Cargo:		60 L

#### **14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS:	No
Danger releasing substance:	Not applicable.

#### **14.6. Special precautions for user**

not relevant

#### **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**

Restrictions on use (REACH, annex XVII):  
Entry 3, Entry 40, Entry 75

##### **National regulatory information**

Water hazard class (D): 2 - obviously 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**

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

Date of preparation / Revised on: 26/02/2024

Version number: 3,08

Replaces version number: 3,07 (22/05/2018)

#### **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.

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

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Skin Irrit. 2; H315	Calculation method
Eye Dam. 1; H318	Calculation method
STOT SE 3; H336	Calculation method

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

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H373	May cause damage to organs through prolonged or repeated exposure.
EUH066	Repeated exposure may cause skin dryness or cracking.

#### 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.)*