

Revision date: 26.02.2024

Panasil Adhesive

Product code: 14101

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1. Identification

Product identifier

Panasil Adhesive

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.

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.

2. Hazard identification

Classification of the substance or mixture

Regulation (EC) No 1272/2008

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. In particular, 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 in accordance with FDA regulations. This product is classified as a medical device. Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (29 CFR § 1910.1200). 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.

Label elements

Regulation (EC) No 1272/2008

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/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.

Other hazards

Formation of potentially explosive vapor/air mixtures is possible.

3. Composition/information on ingredients

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 (Regulation (EC) No 1272/2008)			
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 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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4. First-aid measures

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.

Most important symptoms and effects, whether acute or 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.

Indication of 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.

5. Fire-fighting measures

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.

Special protective equipment and precautions for fire-fighters

Co-ordinate fire-fighting measures to the fire surroundings.
Do not allow to enter into surface water or drains.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

General advice

Remove all sources of ignition.

Environmental precautions

Do not allow to enter into surface water or drains.

Methods and material for containment and cleaning up

Other information

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

Reference to other sections

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

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7. Handling and storage

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.
Wash hands before breaks and after work.
When using do not eat, drink, smoke, sniff.

Further information on handling

Keep locked up and out of reach of children.

Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and store in a cool place.

Hints on joint storage

Keep away from food and drink.

Further information on storage conditions

Protect against:

Specific end use(s)

Not applicable.

8. Exposure controls/Personal protection

Control parameters

Additional advice on limit values

To date, no national critical limit values exist.

Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Disposable gloves
Suitable material: Butyl caoutchouc (butyl rubber)
Wash hands before breaks and after work.

Skin protection

Protective clothing.
Avoid contact with skin, eyes and clothes.
Take off contaminated clothing and wash it before reuse.

Respiratory protection

Respiratory protection is not required when used properly and under normal conditions.
Provide adequate ventilation.

Environmental exposure controls

Do not allow to enter into surface water or drains.

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9. Physical and chemical properties

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 explosive limits:	2,1 vol. %
Upper explosive 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 ³
Relative density:	No data available
Bulk density:	not applicable
Relative vapour density:	No data available
Particle characteristics:	not applicable

Other information

Information with regard to physical hazard classes

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	

10. Stability and reactivity

Reactivity

Vapours can form explosive mixtures with air.

Chemical stability

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

Possibility of hazardous reactions

None by intended use.

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Conditions to avoid

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

Incompatible materials

None by intended use.
Oxidizing agent

Hazardous decomposition products

Formaldehyde

Further information

Heating may cause a fire.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.
non-irritant.
irritant.
Respiratory or skin sensitisation:

ATEmix calculated

ATE (dermal) 11000,0 mg/kg; ATE (inhalation vapour) 58,83 mg/l; ATE (inhalation dust/mist) 10,000 mg/l

CAS No	Chemical name				
	Route of exposure	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

Causes skin irritation.
Causes serious eye damage.

Sensitizing effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

May cause drowsiness or dizziness. (ethyl acetate)

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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

No data available.

Information on other hazards

Further information

Harmful by inhalation and if swallowed.

: Vapours may cause drowsiness and dizziness.

Harmful: may cause lung damage if swallowed.

12. Ecological information

Ecotoxicity

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

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 algae toxicity	ErC50	3,6 mg/l	96 h	GESTIS	

Partition coefficient n-octanol/water

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

Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

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.

13. Disposal considerations

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

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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

14. Transport information

Land transport (ADR/RID)

UN number or ID number: UN 1866
United Nations proper shipping name: RESIN SOLUTION
Transport hazard class(es): 3
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)

UN number or ID number: UN 1866
United Nations proper shipping name: Resin solution
Transport hazard class(es): 3
Packing group: II
 Hazard label: 3



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

Marine transport (IMDG)

UN number or ID number: UN 1866
United Nations proper shipping name: RESIN SOLUTION
Transport hazard class(es): 3
Packing group: II
 Hazard label: 3



Special Provisions: -
 Limited quantity: 5 L
 Excepted quantity: E2

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EmS: F-E, S-E

Air transport (ICAO-TI/IATA-DGR)

UN number or ID number: UN 1866

United Nations proper shipping name: RESIN SOLUTION

Transport hazard class(es): 3

Packing group: II

Hazard label: 3



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

Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

Danger releasing substance: Not applicable.

Special precautions for user

not relevant

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

not applicable

15. Regulatory information

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

Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

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. I MDG: 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).

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NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PNEC: Predicted No Effect Concentration. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

Classification for mixtures and used evaluation method according to GHS

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 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 Advice: Use only by dental professionals.

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