

Safety Data Sheet

according to UK REACH Regulation

Mucopren® Soft

Revision date: 10.03.2026

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

1.1. Product identifier

Mucopren® Soft

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

Use of the substance/mixture

Permanently soft, polyvinyl siloxane liner.

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

Uses advised against

Use by untrained dental personnel and/or unapproved areas of application.

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

Due to the physical form (paste) a classification with H373 is not indicated. Inhalation is not possible. The fillers are not bioavailable and accordingly these substances are not considered in the classification of this product for inhalation hazards according to Article 12, note (b) of CLP Directive 1272/2008.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Preparation of silicone polymers and fillers 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)			
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (nanoform: Nanoform: 2.5 - 50 nm [D50, number distribution]))			10 - <30 (*) %
	272-697-1	014-052-00-7		
	STOT RE 2; H373 EUH066			

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	
68909-20-6	272-697-1	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	10 - <30 (*) %
		inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	

Further Information

(*) The actual concentration is withheld as a trade secret.

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

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

All standard extinguishing agents are suitable.

Unsuitable extinguishing media

None known.

5.2. Special hazards arising from the substance or mixture

None.

5.3. Advice for firefighters

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

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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 (non-mandatory)

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 precautionary 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

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

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)

Apart from the uses mentioned in section 1.2, no other specific uses are foreseen.

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

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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.

Thermal hazards

None.

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:	Paste
Colour:	Base: pink transparent. Catalyst: colourless transparent.
Odour:	odourless
Odour threshold:	not determined

Test method

Melting point/freezing point:	not applicable
Boiling point or initial boiling point and boiling range:	not applicable
Flammability:	not determined
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
pH-Value:	neutral
Viscosity / kinematic:	not determined
Water solubility:	insoluble
Solubility in other solvents	
not determined	
Density (at 20 °C):	1.1 - 1.2 g/cm³
Bulk density:	not applicable
Particle characteristics:	not determined

9.2. Other information

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Information with regard to physical hazard classes

Explosive properties

not Explosive.

Oxidizing properties

None.

Further Information

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.

10.6. Hazardous decomposition products

Formaldehyde

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

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; ATE (inhalation gas) > 20000 ppm

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rabbit		
	inhalation	Data lacking			

Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: 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

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Based on available data, the classification criteria are not met.
no danger of sensitization.

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

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.

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
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica					
	Acute fish toxicity	LC50 mg/l	>1000	96 h	Danio rerio (zebrafish)	
	Acute algae toxicity	ErC50 mg/l	>10000	72 h	Scenedesmus subspicatus	
	Acute crustacea toxicity	EC50 mg/l	>1000	48 h	Daphnia magna (Big water flea)	

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.

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

Do not remove with domestic waste.

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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

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

Other applicable information

No dangerous good in sense of these transport regulations.

SECTION 15: Regulatory information

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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

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,11,12,13,14,16.

Date of preparation / Revised on: 10/03/2026

Version number: 4,02

Replaces version number: 4,01 (23/05/2018)

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.

Key literature references and sources for data

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

Relevant H and EUH statements (number and full text)

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.)

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

1.1. Product identifier

Mucopren adhesive

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

Use of the substance/mixture

Adhesive

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

Uses advised against

Use by untrained dental personnel and/or unapproved areas of application.

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

Eye Irrit. 2; H319

Skin Sens. 1; H317

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

methyl methacrylate

Signal word:

Danger

Pictograms:



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Hazard statements

H225	Highly flammable liquid and vapour.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves and eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P403+P235	Store in a well-ventilated place. Keep cool.
P501	Dispose of contents/container in accordance with local/regional/national international regulations.

Special labelling of certain mixtures

95 - < 100 per cent of the mixture consists of component(s) of unknown acute toxicity (inhalation).
Contains < 1 % of components with unknown hazards to the aquatic environment.

2.3. Other hazards

Formation of potentially explosive vapor/air mixtures is possible.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Polymethyl methacrylate Copolymer in ethyl acetate.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
141-78-6	ethyl acetate			95 - < 100 %
	205-500-4	607-022-00-5	01-2119475103-46	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336 EUH066			
80-62-6	methyl methacrylate			1 - < 5 %
	201-297-1	607-035-00-6	01-2119452498-28	
	Flam. Liq. 2, Skin Irrit. 2, Skin Sens. 1, STOT SE 3; H225 H315 H317 H335			
1330-20-7	xylene			< 1 %
	215-535-7	601-022-00-9	01-2119488216-32	
	Flam. Liq. 3, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2; H226 H332 H312 H315			

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	
141-78-6	205-500-4	ethyl acetate	95 - < 100 %
		inhalation: Data lacking (gases); dermal: LD50 = >20000 mg/kg; oral: LD50 = 5620 mg/kg	
1330-20-7	215-535-7	xylene	< 1 %
		inhalation: LC50 = 19,8 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); dermal: ATE = 1100 mg/kg; oral: LD50 = 5000 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.

Seek medical attention if problems persist.

After contact with skin

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

Change contaminated clothing.

After contact with eyes

If product gets into the eye, keep eyelid open and rinse immediately with large quantities of water, for at least 5 minutes. Subsequently consult an ophthalmologist.

After ingestion

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

Do NOT induce vomiting. Caution if victim vomits: Risk of aspiration!

Have victim drink large quantities of water, with active charcoal if possible. Give sodium sulfate as laxative (1 tablespoon in 1 glass of water).

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

No known symptoms to date.

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

Extinguishing powder

Foam

Carbon dioxide (CO₂)

Unsuitable extinguishing media

Water spray jet

5.2. Special hazards arising from the substance or mixture

Combustible. Vapours are heavier than air and will spread at floor level.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Take precautionary measures against static discharges.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Remove all sources of ignition.

Use personal protection equipment.

For non-emergency personnel

Do not allow to enter into surface water or drains.

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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

Wipe up with absorbent material (eg. cloth, fleece). Clean contaminated articles and floor according to the environmental legislation.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Section 12: Ecological Information (non-mandatory)

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear personal protection equipment (refer to section 8).

Avoid breathing vapours.

Advice on protection against fire and explosion

Take precautionary measures against static discharges.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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

After use replace the closing cap immediately.

Keep only in the original container.

Keep container tightly closed in a cool, well-ventilated place.

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 applicable.

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
141-78-6	Ethyl acetate	200	734		TWA (8 h)	WEL
		400	1468		STEL (15 min)	WEL
80-62-6	Methyl methacrylate	50	208		TWA (8 h)	WEL
		100	416		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

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment. If handled uncovered, arrangements with local exhaust ventilation have to be used.

Individual protection measures, such as personal protective equipment

Eye/face protection

Eye glasses with side protection EN 166

Hand protection

When handling with chemical substances, protective clothing with CE-labels including the four control digits must be worn. Recommended glove articles EN ISO 374

By short-term hand contact Suitable material: NBR (Nitrile rubber).

Thickness of the glove material: 0,38mm

Breakthrough time:: -

By long-term hand contact: PE (polyethylene)

Thickness of the glove material: -

Breakthrough time:: >480 min

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.

Respiratory protection necessary at: aerosol or mist generation.

Suitable respiratory protection apparatus: Full-/half-/quarter-face masks (EN 136/140)

Suitable material: A2, B2, E2, K2, P3

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:	colourless
Odour:	characteristic

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Odour threshold: No data available

		Test method
Melting point/freezing point:	-84 °C	
Boiling point or initial boiling point and boiling range:	76,5 - 77,5 °C	
Flammability:	No data available	ISO 10156
Lower explosion limits:	2,1 vol. %	
Upper explosion limits:	11,5 vol. %	
Flash point:	ca. - 4 °C	DIN 51758
Auto-ignition temperature:	No data available	
Decomposition temperature:	No data available	
pH-Value:	not applicable	
Viscosity / kinematic:	No data available	
Water solubility:	ca. 85 g/L	
(at 20 °C)		
Dissolution rate:	No data available	
Partition coefficient n-octanol/water:	0,73	
Dispersion stability:	No data available	
Vapour pressure:	No data available	
(at 20 °C)		
Vapour pressure:	No data available	
Density (at 20 °C):	> 0,9 g/cm ³	
Relative density:	No data available	
Bulk density:	not applicable	
Relative vapour density:	No data available	g/cm ³
(at 20 °C)		
Particle characteristics:	not applicable	

9.2. 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

none

Other safety characteristics

Viscosity / dynamic:

0,44 mPa·s

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.

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10.5. Incompatible materials

Alkali metals.
Oxidizing agents.

10.6. Hazardous decomposition products

No data available

Further information

Highly flammable. Vapours may form explosive mixtures with air.

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: > 5000 mg/kg Rat

ATEmix tested

	Dose	Species	Source
LD50, oral	5000 mg/kg	Rat	
LD50, dermal	18000 mg/kg	Rabbit	
LC50, inhalation (vapour)	mg/l	not applicable	

ATEmix calculated

ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
141-78-6	ethyl acetate				
	oral	LD50 5620 mg/kg	Rat		
	dermal	LD50 >20000 mg/kg	Rabbit		
	inhalation	Data lacking			
1330-20-7	xylene				
	oral	LD50 5000 mg/kg	Rat	GESTIS	
	dermal	ATE 1100 mg/kg			
	inhalation (4 h) vapour	LC50 19,8 mg/l	Rat	GESTIS	
	inhalation dust/mist	ATE 1,5 mg/l			

Irritation and corrosivity

Serious eye damage/eye irritation: Causes serious eye irritation.
Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Skin corrosion/irritation: not applicable

Sensitising effects

May cause an allergic skin reaction. (methyl methacrylate)
no danger of sensitization.

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)

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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.

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. pneumonia.

SECTION 12: Ecological information

12.1. Toxicity

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

Toxic to aquatic organisms.

Technically correct releases of minimal concentrations to adapted biological sewage treatment facility, will not disturb the biodegradability of activated sludge.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
141-78-6	ethyl acetate					
	Acute fish toxicity	LC50 230 mg/l	96 h	Pimephales promelas		
	Acute algae toxicity	ErC50 >100 mg/l	72 h	Desmodesmus subspicatus		
1330-20-7	xylene					
	Acute algae toxicity	ErC50 3,2 mg/l	72 h	Selenastrum capricornutum	Galassi et al. 1988	

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No indication of bio-accumulation potential.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
1330-20-7	xylene	3,15

BCF

CAS No	Chemical name	BCF	Species	Source
141-78-6	ethyl acetate	30		

12.4. Mobility in soil

The 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 uncontrolled leakage of product into the environment.

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

Land transport (ADR/RID)

14.1. UN number or ID number: UN 1173
14.2. UN proper shipping name: ETHYL ACETATE
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



Classification code: F1
Limited quantity: 1 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 1173
14.2. UN proper shipping name: ETHYL ACETATE
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



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Classification code: F1
 Limited quantity: 1 L
 Excepted quantity: E2

Marine transport (IMDG)

14.1. UN number or ID number: UN 1173
14.2. UN proper shipping name: ETHYL ACETATE
14.3. Transport hazard class(es): 3
14.4. Packing group: II
 Hazard label: 3



Special Provisions: -
 Limited quantity: 1 L
 Excepted quantity: E2
 EmS: F-E, S-D

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number: UN 1173
14.2. UN proper shipping name: ETHYL ACETATE
14.3. Transport hazard class(es): 3
14.4. Packing group: II
 Hazard label: 3



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

Additional information

The classification was undertaken in accordance with the calculation method governed by the Preparations Directive (1999/45/EC).

National regulatory information

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Water hazard class (D): 3 - highly 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): 1,2,16.

Date of preparation / Revised on: 30/01/2024

Version number: 3,11

Replaces version number: 3,10 (31/10/2023)

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.

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

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Eye Irrit. 2; H319	Calculation method
Skin Sens. 1; H317	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.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
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.)

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

1.1. Product identifier

Mucopren silicone sealant

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

Use of the substance/mixture

Permanently soft, polyvinyl siloxane liner. 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

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) a classification with H373 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).

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica			15 - < 20 %
	272-697-1	014-052-00-7	01-2119379499-16	
	STOT RE 2; H373 EUH066			

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		
68909-20-6	272-697-1	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	15 - < 20 %
	inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 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. In case of troubles or persistent symptoms, consult an ophthalmologist.

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

All standard extinguishing agents are suitable. Water fog. Foam. Carbon dioxide (CO2).

Unsuitable extinguishing media

None known.

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

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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

For containment

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

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.

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).

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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:	Base: pink transparent. Catalyst: colourless transparent.
Odour:	odourless
Melting point/freezing point:	not applicable
Boiling point or initial boiling point and boiling range:	No data available
Flammability:	No data available
Lower explosion limits:	No data available
Upper explosion limits:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH-Value:	neutral
Viscosity / kinematic:	No data available
Water solubility:	insoluble
Dissolution rate:	No data available
Partition coefficient n-octanol/water:	No data available
Dispersion stability:	No data available
Vapour pressure:	No data available
Vapour pressure:	No data available
Density (at 20 °C):	1.1 - 1.2 g/cm ³
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

Explosive properties

not Explosive.

Oxidizing properties

not applicable

Further Information

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.

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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

strong base
Oxidising agent, strong

10.6. Hazardous decomposition products

Formaldehyde

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

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
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rabbit		
	inhalation	Data lacking			

Irritation and corrosivity

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.

SECTION 12: Ecological information

12.1. Toxicity

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

product has not been tested.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica					
	Acute fish toxicity	LC50 mg/l	>1000	96 h	Danio rerio (zebrafish)	
	Acute algae toxicity	ErC50 mg/l	>10000	72 h	Scenedesmus subspicatus	
	Acute crustacea toxicity	EC50 mg/l	>1000	48 h	Daphnia magna (Big water flea)	

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

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. 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.

Inland waterways transport (ADN)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

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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

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

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 40, Entry 70

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

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

Date of preparation / Revised on: 14/05/2024

Version number: 3,04

Replaces version number: 3,03 (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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Relevant H and EUH statements (number and full text)

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.)