

according to Regulation (EC) No 1907/2006

Permaliner®

Revision date: 18.12.2020

Product code: 10820

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

1.1. Product identifier

Permaliner®

UFI: 9YXX-K00D-100V-4MU9

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

Use of the substance/mixture

Relining material for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name:	DETAX GmbH & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	
	+49 7243/510-0	
	This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)	

Importer / Distributer

Company name:	Ivoclar Vivadent Pty Ltd	
Place:	1-5 Overseas Drive Noble Park North VIC 3174	
Telephone:	+61 3 9795 9599	Telefax: Fax: +61 3 9795 9645
e-mail:	info@ivoclarvivadent.com	

1.4. Emergency telephone number:

13 11 26
Poisons Hotline (24 hours / 7 days)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:
Respiratory or skin sensitisation: Skin Sens. 1
Hazardous to the aquatic environment: Aquatic Chronic 3
Hazard Statements:
May cause an allergic skin reaction.
Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

dibenzoyl peroxide; benzoyl peroxide

Signal word: Warning

Pictograms:



Hazard statements

H317 May cause an allergic skin reaction.

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H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P501 Dispose of contents/ container in accordance with local and national regulations.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Contains: polydimethylsiloxane + inert filler and pigment + part of organic peroxide

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
94-36-0	dibenzoyl peroxide; benzoyl peroxide			1 - < 5 %
	202-327-6	617-008-00-0	01-2119511472-50	
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1; H241 H319 H317 H400 H410			
540-97-6	Dodecaemthylcyclhexasiloxane			< 0,5 %
	208-762-8		01-2119517435-42	
75-09-2	dichloromethane, (see methylene chloride)			< 1 %
	200-838-9	602-004-00-3		
	Carc. 2, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H351 H315 H319 H336			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

 Rinse mouth immediately and drink plenty of water.
 Do not induce vomiting. If you feel unwell, seek medical advice.

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

No information available.

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

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

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

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.

Do not allow entering drains or surface water.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. 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

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

No special measures are necessary.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed.

Hints on joint storage

Do not store with combustible materials. Do not store with spontaneous flammable materials.

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

7.3. Specific end use(s)

Silicone material for denture relinings.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

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8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
75-09-2	Dichloromethane	100	353		TWA (8 h)	WEL
		200	706		STEL (15 min)	WEL

Biological Monitoring Guidance Values (EH40)

CAS No	Substance	Parameter	Value	Test material	Sampling time
75-09-2	Dichloromethane	carbon monoxide	30 ppm	end-tidal breath	Post shift

8.2. Exposure controls

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.
Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. 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.

Suitable are gloves of the following material: NR (natural rubber, natural latex), CR (polychloroprene, chloroprene rubber), NBR (Nitrile rubber), Butyl caoutchouc (butyl rubber), FKM (fluoro rubber), PVC (Polyvinyl chloride)

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Paste
 Colour: gingiva coloured
 Odour: odourless

Test method

pH-Value: not determined

Changes in the physical state

Melting point: not determined

Initial boiling point and boiling range: not determined

Flash point: >100 °C DIN 51755

Flammability

Solid: not determined

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Gas:	not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Ignition temperature:	>200 °C DIN 51794
Auto-ignition temperature	
Solid:	not determined
Gas:	not applicable
Decomposition temperature:	>250 °C
Oxidizing properties	
Not oxidizing.	
Vapour pressure: (at 20 °C)	<1 hPa
Density (at 20 °C):	1,1 g/cm ³ DIN 51757
Water solubility:	insoluble
Solubility in other solvents	
not determined	
Partition coefficient:	not determined
Vapour density:	not determined
Evaporation rate:	not determined

9.2. Other information

Solid content: not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with : combustible materials.

10.4. Conditions to avoid

The material may autopolymerise at a temperature exceeding 60°C/ 140°F. Therefore keep containers tightly closed in a refrigerator at 2°C-12°C/ 36°F-54°F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

At a temperature of approx. 150°C/ 302°F a small amount of formaldehyde can be released by oxidative degradation.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
94-36-0	dibenzoyl peroxide; benzoyl peroxide				
	oral	LD50 >5000 mg/kg	Rat		
	inhalation (4 h) aerosol	LC50 24,3 mg/l	Rat	OECD 403	
540-97-6	Dodecaemthylcyclohexasiloxane				
	oral	LD50 2000 mg/kg	Rat		
	dermal	LD50 2000 mg/kg	Rat		
75-09-2	dichloromethane, (see methylene chloride)				
	oral	LD50 >2000 mg/kg	Rat	ECHA	
	dermal	LD50 >2000 mg/kg	Rat	ECHA	
	inhalation (4 h) vapour	LC50 52 mg/l	Rat	TOXNET	

Irritation and corrosivity

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

Sensitising effects

May cause an allergic skin reaction. (dibenzoyl peroxide; benzoyl peroxide)

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.

Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
94-36-0	dibenzoyl peroxide; benzoyl peroxide					
	Acute fish toxicity	LC50 mg/l	0,06	96 h	Oncorhynchus mykiss (Rainbow trout)	OECD 203
	Acute algae toxicity	ErC50 mg/l	0,07	72 h	Pseudokirchneriella subcapitata	OECD 201
	Acute crustacea toxicity	EC50	0,11 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202
	Acute bacteria toxicity	(35 mg/l)		0,5 h		OECD 209
75-09-2	dichloromethane, (see methylene chloride)					
	Acute fish toxicity	LC50	193 mg/l	96 h	Pimephales promelas (fathead minnow)	ECOTOX
	Acute algae toxicity	ErC50 mg/l	>660	96 h	Pseudokirchneriella subcapitata	IUCLID
	Acute crustacea toxicity	EC50 mg/l	1682	48 h	Daphnia magna (Big water flea)	IUCLID
	Acute bacteria toxicity	(2,88 mg/l)			Photobacterium phosphoreum	IUCLID

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
94-36-0	dibenzoyl peroxide; benzoyl peroxide				
	OECD 301D/ EEC 92/69/V, C.4-E	71%	28		
	Biodegradable.				
75-09-2	dichloromethane, (see methylene chloride)				
	OECD 301C/ ISO 9408/ EEC 92/69/V, C.4-F	5-26%	28		
	Not readily biodegradable (according to OECD criteria)				

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Dodecamethylcyclohexasiloxane (D6) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for very persistent and very bioaccumulative substances (vPvB) and was included in the candidate list of substances of very high concern (SVHC). According to our knowledge of the state of the art, however, D6 cannot be compared with known persistent, bioaccumulative and toxic (PBT) and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D6 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D6 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

12.6. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN 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:</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:</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:</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.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

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 59: dichloromethane, (see methylene chloride)

Additional information

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

The mixture contains substances of very high concern (SVHC candidates):

Dodecamethylcyclohexasiloxane (D6), CAS no. 540-97-6

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National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
 Water hazard class (D): 2 - obviously hazardous to water
 Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

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

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
 (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 GHS: Globally Harmonized System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service
 LC50: Lethal concentration, 50%
 LD50: Lethal dose, 50%

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H241 Heating may cause a fire or explosion.
 H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H336 May cause drowsiness or dizziness.
 H351 Suspected of causing cancer.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.
 H412 Harmful to aquatic life with long lasting effects.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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