

Safety Data Sheet

according to UK REACH Regulation

VITA VIONIC® DENT RESIN

Revision date: 05.11.2024

Product code: 3141

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

1.1. Product identifier

VITA VIONIC® DENT RESIN

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

Use of the substance/mixture

Lichthärtendes Einkomponentenmaterial zur generativen Herstellung von dentalen Restaurationen

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: DETAX GmbH
Street: Carl-Zeiss-Strasse 4
Place: D-76275 Ettlingen
Telephone: +497243/510-0
E-mail: post@detax.com
Internet: www.detax.com

Supplier

Company name: VITA Zahnfabrik H.Rauter GmbH & Co.KG
Street: Spitalgasse 3
Place: D-79713 Bad Säckingen
Telephone: +49(0)7761-562-0
E-mail: info@vita-zahnfabrik.com
Contact person: regulatory affairs
E-mail: info@vita-zahnfabrik.com
Internet: www.vita-zahnfabrik.com
Responsible Department: Regulatory Affairs

Telefax: +49(0)7761-562-299

1.4. Emergency telephone number:

+1-800-424-9300 (CHEMTREC)

Further Information

Medizinprodukt

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Skin Sens. 1; H317
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

7,7,9(or 7,9,9)
-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecan-1,16-diylbismethacrylat-2-Hydroxyethylmethacrylat
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide
Hydroxypropylmethacrylat
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Signal word: Danger

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Pictograms:



Hazard statements

- H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

- P501 Dispose of contents/container to an appropriate recycling or disposal facility.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P302+P352 IF ON SKIN: Wash with plenty of water and soap.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P273 Avoid release to the environment.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mischung aus Acryl-/Methacrylharzen mit Hilfsstoffen

Relevant ingredients

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
	Alkoxylated phenol derivative, methacrylate terminated			40- < 60%
	Aquatic Chronic 4; H413			
72869-86-4	7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecan-1,16-diylbismethacrylat-2-Hydroxyethylmethacrylat			5 - < 20%
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
6606-59-3	1,6-Hexandioldimethacrylat			5 - < 20%
	Aquatic Chronic 3; H412			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			0,1 < 5 %
	423-340-5	015-189-00-5		
	Skin Sens. 1A, Aquatic Chronic 4; H317 H413			
27813-02-1	Hydroxypropylmethacrylat			0,1 < 5 %
	248-666-3		01-2119490226-37	
	Eye Irrit. 2, Skin Sens. 1; H319 H317			
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			0,1 < 5 %
	278-355-8			
	Repr. 2, Skin Sens. 1, Aquatic Chronic 2; H361f H317 H411			

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

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Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
72869-86-4		7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecan-1,16-diylbismethacrylat2-Hydroxyethylmethacrylat	5 - < 20 %
		dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 5000 mg/kg	
162881-26-7	423-340-5	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	0,1 < 5 %
		dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 2000 mg/kg	
27813-02-1	248-666-3	Hydroxypropylmethacrylat	0,1 < 5 %
		dermal: LD50 = > 5000 mg/kg; oral: LD50 = > 2000 mg/kg	
75980-60-8	278-355-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	0,1 < 5 %
		dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 5000 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Remove the affected person to fresh air and immobilize in a position that facilitates breathing. Seek medical attention if symptoms occur.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Rinse contaminated skin with plenty of water. Remove contaminated clothing and shoes. Consult a doctor if symptoms occur. Seek medical advice immediately.

After contact with eyes

Immediately flush eyes with plenty of water and occasionally lift upper and lower eyelids. Check for contact lenses and remove if present. Seek medical attention if irritation occurs.

After ingestion

Rinse the mouth with water. If the substance has been swallowed and the affected person is conscious, give small amounts of water to drink. Do not induce vomiting unless specifically instructed to do so by medical personnel. Seek medical attention if symptoms occur.

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

No additional information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Match fire extinguishing measures to the surrounding area.

5.2. Special hazards arising from the substance or mixture

The product is not self-igniting. Vapours may form explosive mixtures with air.

5.3. Advice for firefighters

Wear protective clothing. Use self-contained breathing apparatus. Wear complete protective equipment.

Additional information

Use water spray to cool containers. Fire residues and contaminated extinguishing water must be disposed of in accordance with local regulations. Do not allow to enter drains/surface waters/groundwater.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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General advice

Ensure good ventilation/exhaustion at the workplace. Avoid contact with eyes and skin. Wear personal protective equipment.

6.2. Environmental precautions

Do not allow to enter drains/surface waters/groundwater.

6.3. Methods and material for containment and cleaning up

Other information

For safe handling information: see section 7. See Section 8 for information regarding appropriate personal protective equipment. See section 13 for further details on waste treatment.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No further information, see section 7.

Advice on protection against fire and explosion

No further information, see section 7.

Advice on general occupational hygiene

Hygienic measures: Wash hands, arms and face thoroughly after handling chemical products and at the end of the day wash hands, forearms, and face thoroughly after handling chemical products and at the end of the workday, as well as before eating, smoking, and visiting the restroom. Select appropriate methods for removing contaminated clothing. Wash contaminated clothing before reuse. Ensure that eyewash stations and safety showers are available near the work area.

7.2. Conditions for safe storage, including any incompatibilities

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

CAS No	Substance			
DNEL type		Exposure route	Effect	Value
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
Worker DNEL, long-term		dermal	systemic	0,233 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	0,145 mg/m³
Consumer DNEL, long-term		dermal	systemic	0,0833 mg/kg bw/day
Consumer DNEL, long-term		oral	systemic	0,0833 mg/kg bw/day
Worker DNEL, long-term		inhalation	systemic	0,822 mg/m³

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Eye protection Wear eye/face protection.

Hand protection

Wear suitable gloves. When handling chemical products, chemical-resistant, impermeable gloves conforming to a recognized standard must always be worn if a risk assessment so requires. > 8 hours (penetration time): Nitrile rubber

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Skin protection

Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Colour: zahnfarbe

Flash point:

>100 °C

Decomposition temperature:

>=190 °C

Water solubility:

The mixture is not soluble (in water).

Vapour pressure:

<1 hPa

(at 20 °C)

Density (at 20 °C):

1,4 g/cm³

Test method

DIN 51755

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

Not classified as explosive.

Oxidizing properties

Not oxidising.

SECTION 10: Stability and reactivity

10.1. Reactivity

Under normal storage conditions and use, no hazardous reactions will occur.

10.2. Chemical stability

Stable under normal conditions.

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.

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

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
72869-86-4	7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecan-1,16-diylbismethacrylat2-Hydroxyethylmethacrylat				
	oral	LD50 > 5000 mg/kg	Ratte	OECD 401	
	dermal	LD50 > 2000 mg/kg	Ratte	OECD 402	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide				
	oral	LD50 > 2000 mg/kg	Rat	OECD 401	
	dermal	LD50 > 2000 mg/kg	Rat	OECD 402	
27813-02-1	Hydroxypropylmethacrylat				
	oral	LD50 > 2000 mg/kg	Rat	OECD 401	
	dermal	LD50 > 5000 mg/kg	Rabbit		
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 > 5000 mg/kg	Rat		
	dermal	LD50 > 2000 mg/kg	Rat		

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.

Sensitising effects

May cause an allergic skin reaction. (7,7,9(or 7,9,9)

-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecan-1,16-diylbismethacrylat2-Hydroxyethylmethacrylat; phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide; Hydroxypropylmethacrylat; Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide)

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

Harmful to aquatic life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
	Alkoxyated phenol derivative, methacrylate terminated					
	Acute fish toxicity	LC50 >100 mg/l	96 h			
	Acute algae toxicity	ErC50 >100 mg/l	72 h			
	Acute crustacea toxicity	EC50 >100 mg/l	48 h			
72869-86-4	7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahehexadecan-1,16-diylbismethacrylat2-Hydroxyethylmethacrylat					
	Acute fish toxicity	LC50 >100 mg/l	96 h			OECD 203
	Acute algae toxicity	ErC50 >100 mg/l	72 h			OECD 201
	Acute crustacea toxicity	EC50 >100 mg/l	48 h	Daphnia magna	OECD 202	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide					
	Acute fish toxicity	LC50 > 0,09 mg/l	96 h	Danio rerio(Zebrabärbling)	OECD 203	
	Acute algae toxicity	ErC50 > 0,26 mg/l	72 h	Desmodesmussubsp icatus	OECD 201	
	Acute crustacea toxicity	EC50 > 1,175 mg/l	48 h	Daphnia magna	OECD 202	
27813-02-1	Hydroxypropylmethacrylat					
	Acute fish toxicity	LC50 493 mg/l	96 h	Leuciscus idus(Goldorfe)		
	Acute algae toxicity	ErC50 > 97,2 mg/l	72 h	Pseudokirchneriellas ubcapitata	OECD 201	
	Acute crustacea toxicity	EC50 380 mg/l	48 h	Daphnia magna	OECD 202	
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	Acute algae toxicity	ErC50 > 2,01 mg/l	72 h	Pseudokirchneriellas ubcapitata		
	Acute crustacea toxicity	EC50 3,53 mg/l	48 h	Daphnia magna(Großer Wasserfloh)		
	Acute bacteria toxicity	EC50 > 1000 mg/l ()	3 h			

12.2. Persistence and degradability

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CAS No	Chemical name	Method	Value	d	Source
		Evaluation			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide				
	CO2	1%	29		
	The product is: Not readily biodegradable (according to OECD criteria).				
27813-02-1	Hydroxypropylmethacrylat				
		94 %	28		
	The product is: Not readily biodegradable (according to OECD criteria).				
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
		0-10 %	28		
	The product is: Not readily biodegradable (according to OECD criteria).				

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
72869-86-4	7,7,9(or 7,9,9) -Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecan-1,16-diylbismethacrylat2-Hydroxyethyl methacrylat	3,39
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	5,8
27813-02-1	Hydroxypropylmethacrylat	0,97
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,1

BCF

CAS No	Chemical name	BCF	Species	Source
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl) -phosphine oxide	<5	Cyprinus carpio	OECD 305
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	47-55	Cyprinus carpio	

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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter drains/surface waters/groundwater. Appropriate disposal / Package

SECTION 14: Transport information

Land transport (ADR/RID)

- 14.1. UN number or ID number:**
14.2. UN proper shipping name:
14.3. Transport hazard class(es):
14.4. Packing group:

No dangerous good in sense of this transport regulation.
 No dangerous good in sense of this transport regulation.
 No dangerous good in sense of this transport regulation.
 No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

- 14.1. UN number or ID number:**
14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.
 No dangerous good in sense of this transport regulation.

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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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Restrictions on use (REACH, annex XVII):

Entry 75

Information according to Directive
2012/18/EU (SEVESO III):

E2 Hazardous to the Aquatic Environment

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):

3 - highly hazardous to water

Skin resorption/Sensitization:

Causes allergic hypersensitivity reactions.

SECTION 16: Other information

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Abbreviations and acronyms

Eye Irrit: Eye irritation
 Skin Sens: Skin sensitisation
 Repr: Reproductive toxicity
 Aquatic Chronic: Chronic aquatic hazard
 ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 ATE: Acute Toxicity Estimates
 ADN: European agreement concerning the international carriage of dangerous goods by inland waterways
 BCF: Bioconcentration factor
 CLP: Classification labelling packaging regulation; Regulation (EC) No 1272/2008
 DMEL: Derived minimal effect level
 DNEL: Derived-No effect level
 DPD: Dangerous preparations directive 1999/45/EC
 GHS: Globally harmonized system of classification and labelling of chemicals
 IARC: International agency for research on cancer
 EC50: mean effective concentration, 50%
 IATA: International air transport association
 IMDG: International Maritime Code for Dangerous Goods
 LC50: lethal concentration, 50%
 LD50: lethal dose, 50%
 LOAEL: Lowest observed adverse effect level
 NOAEL: No-Observed adverse effect level
 NOEC: No-Observed effect concentration
 OECD: Organisation for economic Co-operation and development
 PBT: persistent, bioaccumulative and toxic
 PNEC: Predicted No-Effect concentration
 REACH: Registration, evaluation, authorisation and restriction of chemicals regulation (EC) No 1907/2006
 RID: Regulations concerning the international carriage of dangerous goods by rail
 SDS: Safety data sheet
 STP: Sewage treatment plant
 TLM: Median tolerance limit
 vPvB: very persistent and very bioaccumulative

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

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

Relevant H and EUH statements (number and full text)

H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H361f Suspected of damaging fertility.
 H411 Toxic to aquatic life with long lasting effects.
 H412 Harmful to aquatic life with long lasting effects.
 H413 May cause long lasting harmful effects to aquatic life.

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