

Safety Data Sheet

according to Regulation (EC) No 1907/2006

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

Regulation (EC) No 1272/2008

Skin Sens. 1; H317
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

7,7,9(or 7,9,9)
-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-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 (Regulation (EC) No 1272/2008)			
	Alkoxyliertes Phenol-Derivat, Methacrylat-Terminiert			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-dioxa-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 contact with skin

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Avoid contact with eyes and skin.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

7.2. Conditions for safe storage, including any incompatibilities

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

CAS No	Name of agent	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/m ³
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/m ³

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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.

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 **Test method** DIN 51755

Decomposition temperature:

>=190 °C

Vapour pressure:

<1 hPa

(at 20 °C)

Density (at 20 °C):

1,4 g/cm³

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties

Not oxidising.

SECTION 10: Stability and reactivity

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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-diazahexadecan-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-diazahexadecan-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
	Alkoxyliertes Phenol-Derivat, Methacrylat-Terminiert					
	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-dioxa-5,12-diazahexadecan-1,16-diylbismethacrylat-2-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	Desmodesmus subspicatus	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	Pseudokirchneriella subcapitata	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	Pseudokirchneriella subcapitata		
	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	
27813-02-1	Hydroxypropylmethacrylat				
			94 %	28	
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
			0-10 %	28	

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-dioxa-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 REACH, annex XIII.

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

Appropriate disposal / Package

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.

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)

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- 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

Abbreviations and acronyms

Eye Irrit: Eye irritation

Skin Sens: Skin sensitisation

Repr: Reproductive toxicity

Aquatic Chronic: Chronic aquatic hazard

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)

- 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.

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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.)