

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

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

1.1. Product identifier

VITA VIONIC® BASE RESIN IMPACT

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

Use of the substance/mixture

Lichthärtender Kunststoff zur generativen Herstellung von herausnehmbaren dentalen Prothesenbasen.

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 Irrit. 2; H315
Eye Irrit. 2; H319
Skin Sens. 1; H317
Aquatic Chronic 2; H411

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-diazahehexadecan-1,16-diylbismethacrylat2-Hydroxyethylmethacrylat
Isobornylmethacrylat
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinat

Signal word: Warning

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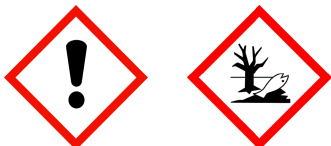
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Pictograms:



Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements

P391	Collect spillage.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P273	Avoid release to the environment.
P272	Contaminated work clothing should not be allowed out of the workplace.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P501	Dispose of contents/container to an appropriate recycling or disposal facility.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mischung aus Acryl-/Methacrylharzen mit Hilfsstoffen

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Relevant ingredients

CAS No	Chemical name	Quantity
	EC No	
	Index No	
	REACH No	
	Classification (Regulation (EC) No 1272/2008)	
41637-38-1	Ethoxyliertes Bisphenol-A-Dimethacrylat	40 - < 60 %
	Aquatic Chronic 4; H413	
72869-86-4	7,7,9(or 7,9,9) -Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-1,16-diylbismethacrylat2-Hydroxyethylmethacrylat	20- < 40%
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411	
7534-94-3	Isobornylmethacrylat	5 - < 20%
	231-403-1	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Aquatic Chronic 3; H315 H319 H335 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	
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	0,1 < 5 %
	272-697-1	014-052-00-7
	STOT RE 2; H373 EUH066	
84434-11-7	Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinat	0,1 < 5 %
	282-810-6	
	Skin Sens. 1, Aquatic Chronic 2; H317 H411	

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	
41637-38-1		Ethoxyliertes Bisphenol-A-Dimethacrylat	40 - < 60 %
		dermal: LD50 = 2000 mg/kg; oral: LD50 = 2000 mg/kg	
72869-86-4		7,7,9(or 7,9,9) -Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-1,16-diylbismethacrylat2-Hydroxyethylmethacrylat	20- < 40%
		dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 5000 mg/kg	
7534-94-3	231-403-1	Isobornylmethacrylat	5 - < 20%
		dermal: LD50 = > 3000 mg/kg; oral: LD50 = > 2000 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	
84434-11-7	282-810-6	Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinat	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

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5.3. Advice for firefighters

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

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:

Boiling point or initial boiling point and
boiling range:

258 °C

Flash point:

>100 °C

Auto-ignition temperature:

385 °C

Vapour pressure:

0,075 hPa

(at 20 °C)

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
41637-38-1	Ethoxyliertes Bisphenol-A-Dimethacrylat				
	oral	LD50 2000 mg/kg	Rat	OECD 423	
	dermal	LD50 2000 mg/kg	Rat	OECD 402	
72869-86-4	7,7,9(or 7,9,9) -Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-1,16-diylobismethacrylat2-Hydroxyethylmethacrylat				
	oral	LD50 > 5000 mg/kg	Ratte	OECD 401	
	dermal	LD50 > 2000 mg/kg	Ratte	OECD 402	
7534-94-3	Isobornylmethacrylat				
	oral	LD50 > 2000 mg/kg	Rat	MSDS	
	dermal	LD50 > 3000 mg/kg	Rabbit	MSDS	
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	
84434-11-7	Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinat				
	oral	LD50 > 5000 mg/kg	Rat		OECD 401
	dermal	LD50 > 2000 mg/kg	Rat		

Irritation and corrosivity

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/eye irritation: Causes serious eye irritation.

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-diylobismethacrylat2-Hydroxyethylmethacrylat; phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide; Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinat)

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

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12.1. Toxicity

Toxic to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
41637-38-1	Ethoxyliertes Bisphenol-A-Dimethacrylat					
	Acute fish toxicity	LC50 >100 mg/l	96 h	Oncorhynchus mykiss	OECD 203	
	Acute algae toxicity	ErC50 >100 mg/l	72 h	Pseudokirchneriellas ubcapitata	OECD 201	
	Acute crustacea toxicity	EC50 >100 mg/l	48 h	Daphnia magna	OECD 202	
72869-86-4	7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-1,16-diylobismethacrylat2-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	
7534-94-3	Isobornylmethacrylat					
	Acute fish toxicity	LC50 1,79 mg/l	96 h		MSDS	
	Acute crustacea toxicity	EC50 > 2,57 mg/l	48 h	Daphnia magna	MSDS	
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	
84434-11-7	Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinat					
	Acute fish toxicity	LC50 1,89 mg/l	96 h	Danio rerio		

12.2. Persistence and degradability

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
41637-38-1	Ethoxyliertes Bisphenol-A-Dimethacrylat			
	OECD 301D/ EEC 92/69/V, C.4-E	24%	28	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			
	CO2	1%	29	

12.3. Bioaccumulative potential

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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

BCF

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

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:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9



Classification code:	M6
Special Provisions:	274 335 375 601
Limited quantity:	5 L
Excepted quantity:	E1
Transport category:	3
Hazard No:	90
Tunnel restriction code:	-

Other applicable information (land transport)

Contains: 7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-1,16-diylbismethacrylat

Inland waterways transport (ADN)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9

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Classification code:	M6
Special Provisions:	274 335 375 601
Limited quantity:	5 L
Excepted quantity:	E1

Marine transport (IMDG)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9



Special Provisions:	274 335 969
Limited quantity:	5 L
Excepted quantity:	E1
EmS:	F-A, S-F

Other applicable information (marine transport)

Contains: 7,7,9(oder 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-1,16-diylbismethacrylat
Flash point: > 100°C

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9



Special Provisions:	A97 A158 A197 A215
Limited quantity Passenger:	30 kg G
Passenger LQ:	Y964
Excepted quantity:	E1
IATA-packing instructions - Passenger:	964
IATA-max. quantity - Passenger:	450 L
IATA-packing instructions - Cargo:	964
IATA-max. quantity - Cargo:	450 L

Other applicable information (air transport)

Contains: 7,7,9(oder 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-1,16-diylbismethacrylat

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Yes



SECTION 15: Regulatory information

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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 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

Skin Irrit: Skin irritation

Eye Irrit: Eye irritation

Skin Sens: Skin sensitisation

STOT SE: Specific target organ toxicity - single exposure

STOT RE: Specific target organ toxicity - repeated exposure

Aquatic Chronic: Chronic aquatic hazard

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

Classification	Classification procedure
Skin Irrit. 2; H315	
Eye Irrit. 2; H319	
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 2; H411	Calculation method

Relevant H and EUH statements (number and full text)

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
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.
EUH066	Repeated exposure may cause skin dryness or cracking.

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