

## Safety Data Sheet

according to UK REACH Regulation

### 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

#### GB CLP Regulation

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

#### GB CLP Regulation

#### Hazard components for labelling

7,7,9(or 7,9,9)  
-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecan-1,16-diylbismethacrylat-2-Hydroxyethylmethacrylat  
Isobornylmethacrylat  
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide  
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinat

Signal word: Warning

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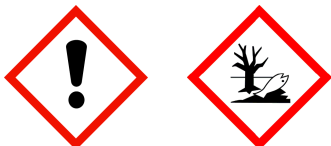
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#### Pictograms:



#### 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 (GB CLP Regulation)			
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 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

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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

##### 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

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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

#### 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

##### **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

258 °C

boiling range:

Flash point:

>100 °C

Auto-ignition temperature:

385 °C

Water solubility:

The mixture is not soluble (in water).

Vapour pressure:

0,075 hPa

(at 20 °C)

#### 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
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-diylbismethacrylat2-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-diylbismethacrylat2-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-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	
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	Desmodesmusubsp 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	
	The product is: Not readily biodegradable (according to OECD criteria).			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			
	CO2	1%	29	
	The product is: Not readily biodegradable (according to OECD criteria).			

#### 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-dioxo-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 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:

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-dioxo-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-diazahehexadecan-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-diazahehexadecan-1,16-diylbismethacrylat

#### 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Yes



#### Other applicable information

Hazchem code: •3Z

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## 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 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

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

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

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.)*