

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

Page 1 of 9

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

Signal word: Warning

Safety Data Sheet

according to Regulation (EC) No 1907/2006

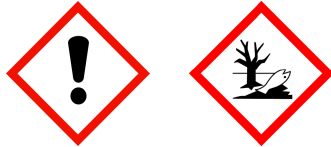
VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

Page 2 of 9

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

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

Page 3 of 9

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

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

Page 4 of 9

5.2. Special hazards arising from the substance or mixture

Vapours may form explosive mixtures with air.

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

258 °C

boiling range:

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.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

Page 5 of 9

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

| 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.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

Page 6 of 9

Aspiration hazard

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

SECTION 12: Ecological information

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 | |

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

Page 7 of 9

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-diazahehexadecan-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(oder 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecan-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

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

Page 8 of 9



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

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC® BASE RESIN IMPACT

Revision date: 01.10.2024

Product code: 3137

Page 9 of 9

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.)