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

1.1. Product identifier

VITA VIONIC® TRY-IN 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 wie provisorischen Kronen und Brücken.

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

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 2; H411

Full text of hazard statements: see SECTION 16.

2.2. Label elements

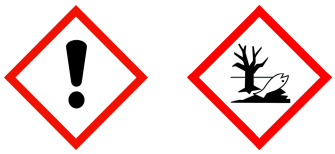
GB CLP Regulation

Hazard components for labelling

7,7,9(or 7,9,9)
-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-1,16-diylbismethacrylat2-Hydroxyethylmethacrylat
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide
2-hydroxyethyl methacrylate
Hydroxypropylmethacrylat
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Signal word: Warning

Pictograms:



Hazard statements

H317	May cause an allergic skin reaction.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements

P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P501	Dispose of contents/container to an appropriate recycling or disposal facility.
P391	Collect spillage.
P362+P364	Take off contaminated clothing and wash it before reuse.
P302+P352	IF ON SKIN: Wash with plenty of Water..
P273	Avoid release to the environment.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

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-dioxa-5,12-diazahexadecan-1,16-diylbismethacrylat2-Hydroxyethylm ethacrylat			20- < 40%
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
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			
6606-59-3	1,6-Hexandioldmethacrylat			0,1 < 5 %
	Aquatic Chronic 3; H412			
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			
868-77-9	2-hydroxyethyl methacrylate			0,1 - < 5 %
	212-782-2	607-124-00-X	01-2119490169-29	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			

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		
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		
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		
868-77-9	212-782-2	2-hydroxyethyl methacrylate	0,1 - < 5 %
	dermal: LD50 = > 5000 mg/kg; oral: LD50 = 5564 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

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

Skin protection

Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Colour: zahnfarben

		Test method
Boiling point or initial boiling point and boiling range:	315 °C	
Flash point:	>93 °C	DIN 51755
Auto-ignition temperature:	445 °C	
Decomposition temperature:	>=190 °C	
Water solubility:	The mixture is not soluble (in water).	
Vapour pressure: (at 20 °C)	<1 hPa	
Density (at 20 °C):	1,1 g/cm³	

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.

10.3. Possibility of hazardous reactions

Reacts with : Oxidising agent

10.4. Conditions to avoid

Reacts with :UV radiation/sunlight

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

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		
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 5564 mg/kg	Rat		
	dermal	LD50 > 5000 mg/kg	Rabbit		

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; 2-hydroxyethyl methacrylate)

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

Toxic to aquatic life with long lasting effects.

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] | [d]	Species	Source	Method
	Alkoxylated 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-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	Daphina 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	Desmodesmussubspicatus	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			
868-77-9	2-hydroxyethyl methacrylate						
	Acute fish toxicity	LC50	> 100 mg/l	96 h	Oryzias latipes		OECD 203
	Acute algae toxicity	ErC50	836 mg/l		Selenastrumcapricornutum		OECD 201
	Acute crustacea toxicity	EC50	380 mg/l	48 h	Daphina magna		OECD 202

12.2. Persistence and degradability

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).			
868-77-9	2-hydroxyethyl methacrylate			
		92-100%	14	

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 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(oder 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

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

Danger releasing substance: 7,7 -Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecan-1,16-dylbismethacrylat

Other applicable information

Hazchem code: •3Z

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

Changes

This data sheet contains changes from the previous version in section(s): 2,3,4,5,6,7,8,9,10,13,14,15,16.

Abbreviations and acronyms

Skin Irrit: Skin irritation
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 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.
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.)