

Safety Data Sheet

according to Regulation (EG) Nr. 1907/2006

smartrepair® rosa

Revision date: 14.08.2023

Product code: 922

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

1.1. Product identifier

smartrepair® rosa

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

Use of the substance/mixture

Ligth curing repair material for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH		
Street:	Carl-Zeiss-Straße 4		
Place:	D-76275 Ettlingen		
Telephone:	+49 7243/510-0	Telefax:	+49 7243/510-100
E-mail:	post@detax.com		
Internet:	www.detax.com		
Responsible Department:	This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)		
	+1-800-424-9300 (CHEMTREC worldwide)		

1.4. Emergency telephone number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EG) Nr. 1272/2008

Skin Sens. 1; H317

Aquatic Chronic 2; H411

Full text of hazard statements: see SECTION 16.

2.2. Label elements

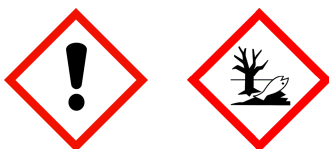
Regulation (EG) Nr. 1272/2008

Hazard components for labelling

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
3,3,5-trimethylcyclohexyl methacrylate
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate
phenyl bis(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

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.

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P362+P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.
P501 Dispose of contents/container to according to local and applicable legislation of dispose of waste.

Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

Mixture of acrylic/ methacrylic resins with auxilliary matters.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EG) Nr. 1272/2008)			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate			60 - < 80 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
6606-59-3	1,6-hexanediol dimethacrylate			5 - < 20 %
	229-551-7			
	Aquatic Chronic 3; H412			
7779-31-9	3,3,5-trimethylcyclohexyl methacrylate			5 - < 20 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1B, STOT SE 3, Aquatic Chronic 2; H315 H319 H317 H335 H411			
84434-11-7	Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate			0.1 - < 5 %
	282-810-6		01-2119987994-10	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
2067275-86-7	1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-,polymer with oxirane, 4-(dimethylamino)benzoate			0.1 - < 5 %
	Skin Sens. 1B, Aquatic Chronic 4; H317 H413			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			< 0.1 %
	423-340-5	015-189-00-5	01-2119489401-38	
	Skin Sens. 1A, Aquatic Chronic 4; H317 H413			

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	276-957-5	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	60 - < 80 %
	dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg		
84434-11-7	282-810-6	Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate	0.1 - < 5 %
	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 %
	dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg		

SECTION 4: First aid measures

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4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink 1 glass of water. Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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Advice on safe handling

No special measures are necessary.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

Keep away from spontaneous flammable or combustible substances.

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs. Keep away from all kind of light. An inert gas blanket should not be applied, because the stability of the product depends on the presence of oxygen (air).

7.3. Specific end use(s)

Dental repair material.

For use by trained specialist staff.

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

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: Butyl caoutchouc (butyl rubber)

Skin protection

Use of protective clothing. Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Paste , low-viscosity
Colour:	pink
Odour:	characteristic

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	240,6 °C

Test method

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Flammability:	not determined
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	>93 °C DIN 51755
Auto-ignition temperature:	445 °C
Decomposition temperature:	not determined
pH-Value:	not determined
Viscosity / kinematic:	not determined
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.
Solubility in other solvents	
not determined	
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	0,00000232 hPa
(at 20 °C)	
Density (at 20 °C):	1,1 g/cm³ DIN 51757
Relative vapour density:	not determined
Particle characteristics:	not applicable

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

Viscosity / dynamic: (at 23 °C)

6500 mPa·s Rheostress

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Ultra-violet light and daylight initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of light. Keep at temperature not exceeding 25°C/ 77°F.

10.5. Incompatible materials

Reacts with : oxidising agents, radicals forming substances or heavy metal ions.

10.6. Hazardous decomposition products

In case of fire, acrid acrylic fumes may occur.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EG) Nr. 1272/2008

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Acute toxicity

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

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

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-diazahexadecane-1,16-diyl bismethacrylate				
	oral	LD50 >5000 mg/kg	Rat	OECD 401	
	dermal	LD50 >2000 mg/kg	Rat	OECD 402	
84434-11-7	Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate				
	oral	LD50 >5000 mg/kg	Rat		OECD 401
	dermal	LD50 >2000 mg/kg	Rat		
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	

Irritation and corrosivity

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-diazahexadecane-1,16-diyl bismethacrylate; 3,3,5-trimethylcyclohexyl methacrylate; Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate; 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl) -,polymer with oxirane, 4-(dimethylamino)benzoate; phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide)

Carcinogenic/mutagenic/toxic effects for reproduction

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.

11.2. Information on other hazards

Other information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Toxic to aquatic life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate					
	Acute fish toxicity	LC50 mg/l	10,1	96 h		OECD 203
	Acute algae toxicity	ErC50 mg/l	0,21	72 h		OECD 201
	Acute crustacea toxicity	EC50 mg/l	>1,2	48 h	Daphnia magna (Big water flea)	OECD 202
84434-11-7	Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate					
	Acute fish toxicity	LC50 mg/l	1,89	96 h	Danio rerio	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide					
	Acute fish toxicity	LC50 mg/l	>0,09	96 h	Danio rerio (zebrafish)	OECD 203
	Acute algae toxicity	ErC50 mg/l	>0,26	72 h	Desmodesmus subspicatus	OECD 201
	Acute crustacea toxicity	EC50 mg/l	>1,175	48 h	Daphnia magna (Big water flea)	OECD 202
	Crustacea toxicity	NOEC mg/l	>0,008	21 d	Daphnia magna (Big water flea)	OECD 211
	Acute bacteria toxicity	(EC50 mg/l)	>100	3 h	OECD 209	

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			
	CO ₂ formation (% of the theoretical value).	1%	29	
	Not readily biodegradable (according to OECD criteria)			

12.3. Bioaccumulative potential

The product has not been tested.

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-diazahexadecane-1,16-diyl bismethacrylate	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 (Common Carp)	OECD 305

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

Not identified as PBT/ vPvB substances

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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.

12.7. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

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-diazahehexadecane-1,16-diylbismethacrylate

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

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Excepted quantity: E1
EmS: F-A, S-F

Other applicable information (marine transport)

Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

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(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Yes

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

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to 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.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

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Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).
Skin Irrit: Skin irritation
Eye Irrit: Eye irritation
Skin Sens: Skin sensitisation
STOT SE: Specific target organ toxicity - single exposure
Aquatic Chronic: Chronic aquatic hazard

Classification for mixtures and used evaluation method according to Regulation(EG) Nr. 1272/2008

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.
H335 May cause respiratory irritation.

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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.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

Identified uses

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
1	Gewerblich	-	-	-	-	-	-	-	2

LCS: Life cycle stages

PC: Product categories

ERC: Environmental release categories

TF: Technical functions

SU: Sectors of use

PROC: Process categories

AC: Article categories

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