

Safety Data Sheet

according to Regulation (EC) No 1907/2006

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Revision date: 24.09.2020 Product code: 10133 Page 1 of 9

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

1.1. Product identifier

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

Use of the substance/mixture

Ligth curing composite material for use in dentistry., Dental modelling resin

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: DETAX GmbH & Co. KG
Street: Carl-Zeiss-Strasse
Place: D-76275 Ettlingen
Telephone: +49 7243/510-0

Felephone: +49 7243/510-0 Telefax: +49 7243/510-100

e-mail: post@detax.de
Internet: www.detax.de
Responsible Department: Emergency number:

+49 7243/510-0

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.)

Importer / Distributer

Company name: Ivoclar Vivadent Ltd

Place: PO Box 303011, North Harbour, Auckland, 0751

Telephone: +64 9 914 9999 Telefax: +64 9 914 9990

<u>1.4. Emergency telephone</u> 0800 764 766 Poison Hotline (24 hours / 7 days) <u>number:</u> NZ: National Poison Centre (New Zealand)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2 Respiratory or skin sensitisation: Skin Sens. 1

Reproductive toxicity: Repr. 1B

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May damage fertility or the unbornchild.
Harmful to aquatic life with long lasting effects.

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-diazahexadecane-1,16-diyl bismethacrylate 2-

Ethylhexyl 4-(dimethylamino)benzoate

Signal word: Danger



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Pictograms:





Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.

H360 May damage fertility or the unborn child.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P201 Obtain special instructions before use.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing

protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P308+P313 IF exposed or concerned: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents/ container in accordance with local and national regulations.

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			
	EC No	Index No	REACH No	
	GHS Classification			
	aliphatic polyestertriurethane triacrylate			
	Skin Irrit. 2, Eye Irrit. 2; H315 H319			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate			1 - < 5 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate			< 1,5 %
	244-289-3		01-2120766649-35	
	Repr. 1B; H360			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. Medical treatment necessary.





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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

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink plenty of water. Induce vomiting when the affected person is not unconscious. Medical treatment necessary.

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

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

Absorb with liquid-binding material (e.g. 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

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.



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7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations. Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs. Keep away from all kind of ligth. An inert gas blanket should not be applied, because the stability of the product depends on the presence of oxygen (air).

Hints on joint storage

Keep away from spontaneous flammable or combustible substances.

Further information on storage conditions

Keep away from all kind of ligth. An inert gas blanket should not be applied, because the stability of the product depends on teh presence of oxygen (air).

7.3. Specific end use(s)

Dental modelling resin

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

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.

Eye/face protection

Suitable eye protection: goggles.

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

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 Colour: red

Odour: characteristic

Test method

pH-Value: not determined

Changes in the physical state

Melting point: not determined



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Initial boiling point and boiling range: not determined

Flash point: >100 °C DIN 51755

Flammability

Solid: not applicable
Gas: not applicable

Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined Upper explosion limits: not determined

Auto-ignition temperature

Solid: not applicable
Gas: not applicable
Decomposition temperature: not determined

Oxidizing properties

Not oxidizing.

Vapour pressure: <1 hPa

(at 20 °C)

Density (at 20 °C): 1,25 g/cm³ DIN 51757

Water solubility: practically insoluble

Solubility in other solvents

not determined

Partition coefficient: not determined

Vapour density: not determined

Evaporation rate: not determined

9.2. Other information

Solid content: not determined

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

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

10.4. Conditions to avoid

Ultra-violet ligth and dayligth 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

No information available.

10.6. Hazardous decomposition products

In case of fire, acrid acrylic fumes mayoccur.

SECTION 11: Toxicological information

11.1. Information on toxicological effects



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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.

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	
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate				
	oral	LD50 14,900 mg/kg	Rat		

Irritation and corrosivity

Causes skin 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-diazahexadecane-1,16-diyl bismethacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

May damage fertility or the unborn child. (2-Ethylhexyl 4-(dimethylamino)benzoate)

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: 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.

Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP]. Special hazards arising from the substance or mixture!

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.



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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-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate				
	Acute crustacea toxicity	EC50 >1,2 mg/l	48 h Daphnia magna (Big water flea)	OECD 202	
21245-02-3	2-3 2-Ethylhexyl 4-(dimethylamino)benzoate				
	Acute fish toxicity	LC50 0,235 mg/l	96 h QSAR		
	Acute algae toxicity	ErC50 <0,015 mg/l	72 h Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50 >0,031 mg/l	48 h Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(1000 mg/l)	3 h Activated sludge		

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identivied as PBT/ vPvB substances

12.6. 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

@1301.B130039 Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

Marine transport (IMDG)



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14.1. UN number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBCCode

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

Classified as Hazardous according to the criteria of the National Occupational Health and Safety

Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008]

3rd edition.

Standard for the Uniform Scheduling of Medicines and Poisons.

Carcinogen classification under WHS Regulation 2011, Schedule 10.

Notification status in accordance with section 3 and current national legislation.

HSNO Approval: HSR003747

EPA NZ Classes of hazardous properties:

Classification 6.8B Suspected human reproductive or developmental toxicants

Classification 8.1A Corrosive to metals

Information according to 2012/18/EU (SEVESO III):

Additional information

Not subject to 2012/18/EU (SEVESO III)

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC



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15.2. Chemical safety assessment

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

SECTION 16: Other information

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

@1602.B016012

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

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Classification	Classification procedure	
Skin Irrit. 2; H315	Calculation method	
Eye Irrit. 2; H319	Calculation method	
Skin Sens. 1; H317	Calculation method	
Repr. 1B; H360	Calculation method	
Aquatic Chronic 3; H412	Calculation method	

Relevant H and EUH statements (number and full text)

H315	Causes skin imitation.
H317	May cause an allergic skin reaction.
H319	Causes serious eve irritation



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H360 May damage fertility or the unborn child.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

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.

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