

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Renamel Microhybrid

Revision date: 21.08.2024

Product code: 616xxx606xxx613xxx

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Renamel Microhybrid

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

dental use

1.3. Details of the supplier of the safety data sheet**Manufacturer**

Company name: Deltamed GmbH .
Street: Raiffeisenstraße 8a
Place: 61169 Friedberg
Telephone: +49 6031 7283-0
E-mail: info@deltamed.de
Internet: www.deltamed.de
Responsible Department: F&E
Telefax: +49 6031 7283-29
Telefax +49 6031 7283-29

Supplier

Company name: COSMEDENT, Inc.
Street: 401 North Michigan Avenue Ste . 2500
Place: USA-IL 60611 Chicago
Telephone: 1-800-621-6729
Contact person: Mary Nowak
E-mail: mary@cosmedent.com
Internet: cosmedent.com
Telephone: 312-644-9586

1.4. Emergency telephone number:

312-644-9586

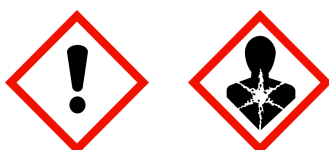
SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No 1272/2008**

Skin Sens. 1; H317
Repr. 1B; H360FD
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements**Regulation (EC) No 1272/2008****Hazard components for labelling**

urethane dimethacrylate (UDMA)
Diboron trioxide (B2O3)
1,4 Butanediol dimethacrylate (1,4-BDDMA)

Signal word: Danger**Pictograms:**

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Hazard statements

H317 May cause an allergic skin reaction.
 H360FD May damage fertility. May damage the unborn child.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P201 Obtain special instructions before use.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/protective clothing/eye protection.
 P302+P352 IF ON SKIN: Wash with plenty of water and soap.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P501 Dispose of contents/container in accordance with local regulation.

Special labelling of certain mixtures

Restricted to professional users.

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
 Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of acrylic resins, fillers and initiators.

Relevant ingredients

CAS No	Chemical name	Quantity
	EC No	Index No
		REACH No
	Classification (Regulation (EC) No 1272/2008)	
72869-86-4	urethane dimethacrylate (UDMA)	< 30 %
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411	
1303-86-2	Diboron trioxide (B2O3)	< 10 %
	215-125-8	005-008-00-8
	Repr. 1B; H360FD	
2082-81-7	1,4 Butanediol dimethacrylate (1,4-BDDMA)	< 25 %
	Skin Sens. 1B; 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		urethane dimethacrylate (UDMA)	< 30 %
		inhalation: LC50 = >5 mg/l (dusts or mists); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
1303-86-2	215-125-8	Diboron trioxide (B2O3)	< 10 %
		oral: LD50 = 3163 mg/kg	
2082-81-7		1,4 Butanediol dimethacrylate (1,4-BDDMA)	< 25 %
		dermal: LD50 = > 3000 mg/kg; oral: LD50 = > 5000 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

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General information

Medical treatment is necessary if symptoms occur which are obviously caused by skin or eye contact with the product or by inhalation of its vapours. Take off all contaminated clothing immediately.

After inhalation

Provide fresh air. Medical treatment necessary.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

After ingestion

Do NOT induce vomiting. Medical treatment necessary.

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**

Foam, Extinguishing powder, Carbon dioxide, Water spray.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide, Carbon dioxide, Hazardous decomposition products.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

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**Other information**

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

Provide adequate ventilation.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking.

Advice on general occupational hygiene

Avoid contact with skin, eyes and clothes. 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 or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Protect from the action of light. Keep only in the original container at a temperature between 4 – 24 °C. Can polymerize with intense heat release.

Hints on joint storage

Do not store together with:

Oxidising agent

Food

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

CAS No	Name of agent	Exposure route	Effect	Value
72869-86-4	urethane dimethacrylate (UDMA)			
Worker DNEL, long-term		dermal	systemic	1,3 mg/kg bw/day
Worker DNEL, long-term		inhalation	systemic	3,3 mg/m ³

PNEC values

CAS No	Name of agent	Value
72869-86-4	urethane dimethacrylate (UDMA)	
Freshwater		0,01 mg/l
Marine water		0,001 mg/l
Freshwater sediment		4,56 mg/kg
Marine sediment		0,46 mg/kg
Micro-organisms in sewage treatment plants (STP)		3,61 mg/l
Soil		0,91 mg/kg

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

tightly fitting goggles

Hand protection

Gloves should be replaced regularly, especially after extended contact with the product. For each work-place a suitable glove type has to be selected.

Skin protection

Wear suitable protective clothing.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	pasty	
Colour:	various, depending on coloration	
Odour:	hardly noticeable	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		not determined
Flammability:		not determined
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Flash point:		not determined
Auto-ignition temperature:		not determined
Decomposition temperature:		not determined
pH-Value:		not determined
Viscosity / kinematic:		not determined
Water solubility:		not determined
Solubility in other solvents		not determined
Partition coefficient n-octanol/water:		not determined
Vapour pressure:		not determined
Density:		not determined
Relative vapour density:		not determined
Particle characteristics:		not applicable

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid:	not applicable
Gas:	not applicable

Other safety characteristics

Evaporation rate:	not determined
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

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

10.4. Conditions to avoid

Protect from the action of light. Keep only in the original container at a temperature between 4 – 24 °C. Can polymerize with intense heat release.

10.5. Incompatible materials

Oxidising agent, Reducing agent, Heavy metals, Acids, Alkali (lye).

10.6. Hazardous decomposition products

No known hazardous decomposition products.

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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.

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	urethane dimethacrylate (UDMA)				
	oral	LD50 >5000 mg/kg	Rat	OECD 401	
	dermal	LD50 >2000 mg/kg	Rat	OECD 402	
	inhalation (4 h) dust/mist	LC50 >5 mg/l			
1303-86-2	Diboron trioxide (B2O3)				
	oral	LD50 3163 mg/kg	Mice	GESTIS	
2082-81-7	1,4 Butanediol dimethacrylate (1,4-BDDMA)				
	oral	LD50 > 5000 mg/kg	Rat	OECD 401	
	dermal	LD50 > 3000 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. (urethane dimethacrylate (UDMA); 1,4 Butanediol dimethacrylate (1,4-BDDMA))

Possible sensitization in case of persons suffering from hypersensitivity.

Carcinogenic/mutagenic/toxic effects for reproduction

May damage fertility. May damage the unborn child. (Diboron trioxide (B2O3))

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.

11.2. Information on other hazards

Further information

Product has not been tested. The statement is derived from the properties of the components.

SECTION 12: Ecological information

12.1. Toxicity

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
72869-86-4	urethane dimethacrylate (UDMA)					
	Acute fish toxicity	LC50 mg/l	10,1	96 h	Danio rerio (zebrafish)	OECD 203
	Acute algae toxicity	ErC50 mg/l	>0,68	72 h	Desmodesmus subspicatus	OECD 201
	Acute crustacea toxicity	EC50 mg/l	>1,2	48 h	Daphnia magna (Big water flea)	
1303-86-2	Diboron trioxide (B2O3)					
	Acute crustacea toxicity	EC50 mg/l	370 - 490	48 h	Daphnia Magna	IUCLID

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
72869-86-4	urethane dimethacrylate (UDMA)				
	Biodegradation	22 %	28	OECD 301 F	

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

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

The product has not been tested.

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 uncontrolled discharge of product into the environment. Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities. Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste

List of Wastes Code - contaminated packaging

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste

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Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information**Land transport (ADR/RID)****Other applicable information (land transport)**

No dangerous good in sense of these transport regulations.

Inland waterways transport (ADN)**Other applicable information (inland waterways transport)**

No dangerous good in sense of these transport regulations.

Marine transport (IMDG)**Other applicable information (marine transport)**

No dangerous good in sense of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)**Other applicable information (air transport)**

No dangerous good in sense of these transport regulations.

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

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):
Diboron trioxide (B2O3)

Restrictions on use (REACH, annex XVII):

Entry 30, Entry 75

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

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

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 2,16.
reason of revision: reclassification ingredients by supplier

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Abbreviations and acronyms

- Skin Sens: Skin sensitisation
- Repr: Reproductive toxicity
- Aquatic Chronic: Chronic aquatic hazard
- 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%

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

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Repr. 1B; H360FD	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

- H317 May cause an allergic skin reaction.
- H360FD May damage fertility. May damage the unborn child.
- H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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