

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### Renamel Flowable Microhybrid

Revision date: 21.08.2024

Product code: 701XXX

Page 1 of 9

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

### 1.1. Product identifier

Renamel Flowable 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	Telefax: +49 6031 7283-29
E-mail:	info@deltamed.de	
Internet:	www.deltamed.de	
Responsible Department:	F&E	
	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	Telephone: 312-644-9586
E-mail:	mary@cosmedent.com	
Internet:	cosmedent.com	

### 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

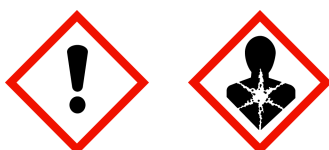
#### Regulation (EC) No 1272/2008

#### Hazard components for labelling

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

Signal word: Danger

Pictograms:



## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### Renamel Flowable Microhybrid

Revision date: 21.08.2024

Product code: 701XXX

Page 2 of 9

#### 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)	< 25 %
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411	
2082-81-7	1,4 Butanediol dimethacrylate (1,4-BDDMA)	< 25 %
	Skin Sens. 1B; H317	
1303-86-2	Diboron trioxide (B2O3)	< 10 %
	215-125-8	005-008-00-8
	Repr. 1B; H360FD	

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)	< 25 %
		inhalation: LC50 = >5 mg/l (dusts or mists); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
2082-81-7		1,4 Butanediol dimethacrylate (1,4-BDDMA)	< 25 %
		dermal: LD50 = > 3000 mg/kg; oral: LD50 = > 5000 mg/kg	
1303-86-2	215-125-8	Diboron trioxide (B2O3)	< 10 %
		oral: LD50 = 3163 mg/kg	

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

## Renamel Flowable Microhybrid

Revision date: 21.08.2024

Product code: 701XXX

Page 3 of 9

**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**

Take up mechanically. 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**

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### Renamel Flowable Microhybrid

Revision date: 21.08.2024

Product code: 701XXX

Page 4 of 9

#### Advice on safe handling

Provide good room 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 <sup>3</sup>

##### 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.

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### Renamel Flowable Microhybrid

Revision date: 21.08.2024

Product code: 701XXX

Page 5 of 9

## 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.

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**Renamel Flowable Microhybrid**

Revision date: 21.08.2024

Product code: 701XXX

Page 6 of 9

**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			
2082-81-7	1,4 Butanediol dimethacrylate (1,4-BDDMA)				
	oral	LD50 > 5000 mg/kg	Rat	OECD 401	
	dermal	LD50 > 3000 mg/kg	Rabbit		
1303-86-2	Diboron trioxide (B2O3)				
	oral	LD50 3163 mg/kg	Mice	GESTIS	

**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**

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**Renamel Flowable Microhybrid**

Revision date: 21.08.2024

Product code: 701XXX

Page 7 of 9

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 490 mg/l	370 -	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

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

## Renamel Flowable Microhybrid

Revision date: 21.08.2024

Product code: 701XXX

Page 8 of 9

**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.



## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### Renamel Flowable Microhybrid

Revision date: 21.08.2024

Product code: 701XXX

Page 9 of 9

#### 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.)*