

according to Regulation (EC) No 1907/2006

**ParaCore**

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**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**

for dental use only

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

Company name: Coltène/Whaledent AG  
Street: Feldwiesenstrasse 20  
Place: CH-9450 Altstätten  
Telephone: +41 (71) 75 75 300  
Telefax: +41 (71) 75 75 301  
e-mail: info.ch@coltene.com  
Internet: www.coltene.com  
Responsible Department: Regulatory Affairs  
msds@coltene.com

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Directive 67/548/EEC or 1999/45/EC**

Indications of danger: Xi - Irritant

R phrases:

May cause sensitisation by skin contact.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory/skin sensitization: Skin Sens. 1

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Causes skin irritation.

May cause an allergic skin reaction.

Causes serious eye irritation.

Harmful to aquatic life with long lasting effects.

**2.2. Label elements****Hazardous components which must be listed on the label**

TEGDMA

Signal word: Warning

Pictograms: GHS07

**Hazard statements**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

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H319 Causes serious eye irritation.  
H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352 IF ON SKIN: Wash with plenty of water.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P337+P313 If eye irritation persists: Get medical advice/attention.

**Additional advice on labelling**

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Hazardous components**

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
276-957-5	UDMA	10 - < 15 %
72869-86-4	R52-53 Aquatic Chronic 3; H412	
221-950-4	TMPTMA	10 - < 15 %
3290-92-4	N - Dangerous for the environment R51-53 Aquatic Chronic 2; H411	
01-2119542176-41		
216-367-7	BISGMA	5 - < 10 %
1565-94-2	Xi - Irritant R36/37/38 Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335	
203-652-6	TEGDMA	1 - < 5 %
109-16-0	Xi - Irritant R36/37/38-43 Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335	
202-327-6	dibenzoyl peroxide; benzoyl peroxide	< 1 %
94-36-0	E - Explosive, O - Oxidizing, Xi - Irritant R3-7-36-43	
617-008-00-0	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 H317	
231-667-8	sodium fluoride	< 1 %
7681-49-4	T - Toxic, Xi - Irritant R25-36/38-32	
009-004-00-7	Acute Tox. 3, Eye Irrit. 2, Skin Irrit. 2; H301 H319 H315 EUH032	

Full text of R-, H- and EUH-phrases: see section 16.

**SECTION 4: First aid measures****4.1. Description of first aid measures**

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**After contact with skin**

After contact with skin, wash immediately with: Water and soap.

**After contact with eyes**

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

**After ingestion**

Seek medical attention if problems persist.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**Water. Foam. Extinguishing powder. Carbon dioxide (CO<sub>2</sub>). Sand.**Additional information**

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

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Avoid contact with skin and eyes.

**6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

**6.3. Methods and material for containment and cleaning up**

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated areas thoroughly.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Avoid contact with skin and eyes.

Restricted to professional users. Keep out of the reach of children.

Observe instructions for use.

**Further information on handling**

After use replace the closing cap immediately.

**7.2. Conditions for safe storage, including any incompatibilities****Further information on storage conditions**

Substances sensitive to light.

Recommended storage temperature: 4 - 8 °C

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

**8.2. Exposure controls****Protective and hygiene measures**

When using do not eat, drink or smoke.

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**Eye/face protection**

Framed glasses.

**Hand protection**

Single-use gloves.

**Skin protection**

Lab apron.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state: Paste  
 Colour: off-white

**Test method****Changes in the physical state**

Density (at 23 °C): 2.1 g/cm<sup>3</sup>  
 Water solubility: insoluble  
 (at 23 °C)

**Solubility in other solvents**

Ethanol. (partially soluble)

**SECTION 10: Stability and reactivity****10.2. Chemical stability**

The product is chemically stable under recommended conditions of storage, use and temperature.

**10.4. Conditions to avoid**

Light.  
 UV-radiation/sunlight.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute toxicity**

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

CAS No	Chemical name				
	Exposure routes	Method	Dose	Species	Source
72869-86-4	UDMA				
	oral	LD50	>2000 mg/kg	Rat	OECD 401
3290-92-4	TMPTMA				
	oral	LD50	> 5000 mg/kg	Rat	literature value
	dermal	LD50	> 3000 mg/kg	Rabbit	literature value
109-16-0	TEGDMA				
	oral	LD50	10837 mg/kg	Rat	literature value
7681-49-4	sodium fluoride				
	oral	LD50	52 mg/kg	Rat	RTECS

**Irritation and corrosivity**

Causes skin irritation.  
 Causes serious eye irritation.

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#### Sensitising effects

May cause an allergic skin reaction. (TEGDMA), (dibenzoyl peroxide; benzoyl peroxide)

## SECTION 12: Ecological information

### 12.1. Toxicity

CAS No	Chemical name	Method	Dose	[h]   [d]	Species	Source
72869-86-4	UDMA					
	Acute fish toxicity	LC50	10.1 mg/l	96 h	Brachydanio rerio (zebra-fish)	OECD 203
3290-92-4	TMPTMA					
	Acute fish toxicity	LC50	2 mg/l	96 h	Oncorhynchus mykiss	literature value
	Acute algae toxicity	ErC50	0.177 mg/l	96 h	Pseudokirchneriella subcapitata	literature value
	Acute crustacea toxicity	EC50	> 9.22 mg/l	48 h	Daphnia magna	
7681-49-4	sodium fluoride					
	Acute fish toxicity	LC50	925 mg/l	96 h	Gambusia affinis	
	Acute algae toxicity	ErC50	850 mg/l	72 h	Desmodesmus subspicatus	
	Acute crustacea toxicity	EC50	338 mg/l	48 h	Daphnia magna	IUCLID

### 12.2. Persistence and degradability

CAS No	Chemical name	Method	Value	d	Source
		Evaluation			
72869-86-4	UDMA				
	OECD 301 F		22%	28	
	Product is not easily biodegradable.				

### 12.3. Bioaccumulative potential

#### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
72869-86-4	UDMA	3.39
3290-92-4	TMPTMA	3.53
1565-94-2	BISGMA	4.94
109-16-0	TEGDMA	1.88

#### Further information

According to the criteria of the EC-classification and labelling "dangerous for the environment" (93/21/EEC) the material/product is not to be classified as dangerous to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Advice on disposal

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

## SECTION 14: Transport information

### Land transport (ADR/RID)

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**14.1. UN number:** ---**Inland waterways transport (ADN)****14.1. UN number:** ---**Marine transport (IMDG)****14.1. UN number:** ---**Air transport (ICAO)****14.1. UN number:** ---**Other applicable information**

Not a hazardous material with respect to these transportation regulations.

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulatory information****Additional information**

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**SECTION 16: Other information****Relevant R-phrases (Number and full text)**

- |          |  |
|----------|--|
| 03       | Extreme risk of explosion by shock, friction, fire or other sources of ignition. |
| 07       | May cause fire.  |
| 25       | Toxic if swallowed.  |
| 32       | Contact with acids liberates very toxic gas.                                     |
| 36       | Irritating to eyes.  |
| 36/37/38 | Irritating to eyes, respiratory system and skin.                                 |
| 36/38    | Irritating to eyes and skin.   |
| 43       | May cause sensitisation by skin contact.   |
| 51       | Toxic to aquatic organisms.  |
| 52       | Harmful to aquatic organisms.  |
| 53       | May cause long-term adverse effects in the aquatic environment.                  |

**Relevant H- and EUH-phrases (Number and full text)**

- |        |  |
|--------|--|
| H241   | Heating may cause a fire or explosion.             |
| H301   | Toxic if swallowed.                                |
| H315   | Causes skin irritation.                            |
| H317   | May cause an allergic skin reaction.               |
| H319   | Causes serious eye irritation.                     |
| H335   | May cause respiratory irritation.                  |
| H411   | Toxic to aquatic life with long lasting effects.   |
| H412   | Harmful to aquatic life with long lasting effects. |
| EUH032 | Contact with acids liberates very toxic gas.       |

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