

according to Regulation (EC) No 1907/2006

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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

**1.4. Emergency telephone number:** +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

**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

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

TEGDMA

**Signal word:** Warning**Pictograms:****Hazard statements**

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

**Precautionary statements**

P282	Wear suitable gloves and eye/face protection.
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P262	Do not get in eyes, on skin, or on clothing.
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**

CAS No	Chemical name	Quantity
	EC No	Index No
	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
3290-92-4	TMPTMA	10 - < 15 %
	221-950-4	01-2119542176-41
	Aquatic Chronic 2; H411	
72869-86-4	UDMA	10 - < 15 %
	276-957-5	
	Aquatic Chronic 3; H412	
1565-94-2	BISGMA	5 - < 10 %
	216-367-7	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335	
109-16-0	TEGDMA	1 - < 5 %
	203-652-6	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335	
1314-13-2	Zinc oxide coated	1 - < 5 %
	215-222-5	
	Skin Irrit. 3, Eye Irrit. 2B, Aquatic Acute 1 (M-Factor = 10); H316 H320 H400	
94-36-0	dibenzoyl peroxide; benzoyl peroxide	< 1 %
	202-327-6	617-008-00-0
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 H317	

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

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

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**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.  
for professional use only 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.

**Eye/face protection**

Framed glasses.

**Hand protection**

Single-use gloves.

**Skin protection**

Lab apron.

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

**Solubility in other solvents**

Ethanol. (partially soluble)

**SECTION 10: Stability and reactivity****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 route	Dose	Species	Source
3290-92-4	TMPTMA			
	oral	LD50 > 5000 mg/kg	Rat	literature value
	dermal	LD50 > 3000 mg/kg	Rabbit	literature value
72869-86-4	UDMA			
	oral	LD50 >2000 mg/kg	Rat	OECD 401
109-16-0	TEGDMA			
	oral	LD50 10837 mg/kg	Rat	literature value
1314-13-2	Zinc oxide coated			
	oral	LD50 7950 mg/kg	Mouse.	literature value

**Irritation and corrosivity**

Causes skin irritation.  
 Causes serious eye irritation.

**Sensitising effects**

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

**SECTION 12: Ecological information****12.1. Toxicity**

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	
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	
72869-86-4	UDMA					
	Acute fish toxicity	LC50	10.1 mg/l	96 h	Brachydanio rerio (zebra-fish)	OECD 203
1314-13-2	Zinc oxide coated					
	Acute fish toxicity	LC50	1.1 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)	literature value
	Acute crustacea toxicity	EC50	0.098 mg/l	48 h	Daphnia magna	literature value

**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
3290-92-4	TMPTMA	3.53
72869-86-4	UDMA	3.39
1565-94-2	BISGMA	4.94
109-16-0	TEGDMA	1.88

**12.5. Results of PBT and vPvB assessment**

not applicable

**Further information**

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**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)****14.1. UN number:** ---**Inland waterways transport (ADN)****14.1. UN number:** ---**Marine transport (IMDG)**

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**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**  
-----**SECTION 16: Other information****Relevant H and EUH statements (number and full text)**

H241	Heating may cause a fire or explosion.
H315	Causes skin irritation.
H316	Causes mild skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H320	Causes eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
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 data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*