

according to Regulation (EC) No 1907/2006

**Cool Temp natural**

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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, N - Dangerous for the environment

R phrases:

Irritating to eyes and skin.

Toxic 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

Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements:

Causes skin irritation.

Causes serious eye irritation.

Toxic to aquatic life with long lasting effects.

**2.2. Label elements**

Signal word:

Warning

Pictograms:

GHS07-GHS09

**Hazard statements**

H315

Causes skin irritation.

H319

Causes serious eye irritation.

H411

Toxic to aquatic life with long lasting effects.

**Precautionary statements**

P280

Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

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present and easy to do. Continue rinsing.

**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	25 - < 30 %
72869-86-4	Xi - Irritant R36/38	
	Skin Irrit. 2, Eye Irrit. 2; H315 H319	
205-016-3	diallyl phthalate	10 - < 15 %
131-17-9	Xn - Harmful, N - Dangerous for the environment R22-50-53	
607-086-00-4	Acute Tox. 4, Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1 (M-Factor = 1); H302 H400 H410	
221-950-4	TMPTMA	1 - < 5 %
3290-92-4	N - Dangerous for the environment R51-53	
	Aquatic Chronic 2; H411	
01-2119542176-41		

Full text of R-, H- and EUH-phrases: 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****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.

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**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 - 23 °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
131-17-9	Diallyl phthalate	-	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.

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

**Solubility in other solvents**

Ethanol. (partially soluble)

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**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**

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
131-17-9	diallyl phthalate				
	oral	ATE	500 mg/kg		
3290-92-4	TMPTMA				
	oral	LD50	> 5000 mg/kg	Rat	literature value
	dermal	LD50	> 3000 mg/kg	Rabbit	literature value

**Irritation and corrosivity**

Causes skin irritation.

Causes serious eye irritation.

**Sensitising effects**

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

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

CAS No	Chemical name					
	Aquatic toxicity	Method	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	

**12.3. Bioaccumulative potential****Partition coefficient n-octanol/water**

CAS No	Chemical name	Log Pow
3290-92-4	TMPTMA	3.53

**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.

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

<b>14.1. UN number:</b>	UN 3082
<b>14.2. UN proper shipping name:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Diallyl phtalate)
<b>14.3. Transport hazard class(es):</b>	9
<b>14.4. Packing group:</b>	III
Hazard label:	9
Classification code:	M6
Special Provisions:	274 335 601
Limited quantity:	5 L
Excepted quantity:	E1
Transport category:	3
Hazard No:	90
Tunnel restriction code:	E

**Marine transport (IMDG)**

<b>14.1. UN number:</b>	UN 3082
<b>14.2. UN proper shipping name:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Diallyl phtalate)
<b>14.3. Transport hazard class(es):</b>	9
<b>14.4. Packing group:</b>	III
Hazard label:	9
Special Provisions:	274, 335
Limited quantity:	5 L
Excepted quantity:	E1
EmS:	F-A, S-F

**Air transport (ICAO)**

<b>14.1. UN number:</b>	UN 3082
<b>14.2. UN proper shipping name:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Diallyl phtalate)
<b>14.3. Transport hazard class(es):</b>	9
<b>14.4. Packing group:</b>	III
Hazard label:	9
Special Provisions:	A97 A158
Limited quantity Passenger:	30 kg G
Passenger LQ:	Y964
Excepted quantity:	E1
IATA-packing instructions - Passenger:	964
IATA-max. quantity - Passenger:	450 L
IATA-packing instructions - Cargo:	964
IATA-max. quantity - Cargo:	450 L

**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)**

22	Harmful if swallowed.
36/38	Irritating to eyes and skin.
50	Very toxic to aquatic organisms.
51	Toxic to aquatic organisms.
53	May cause long-term adverse effects in the aquatic environment.

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

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic 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.)*