# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

077213119

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077213002 077213028 077213036 077213044 077213127 077213135

Stability

Unstable

Stable

Stable

Stable

Stable

Conditions to Avoid

strong oxides, temperature > 25°C

none

Hazardous Decomposition or Byproducts

Hazardous Polymerization

May Occur

Will Not Occur

X none

Cool Temp

Section	VI	-	Health	Hazard	Data

Routes of Entry Inhalation Skin Ingestion

Health Hazards (Acute and Chronic) Unpolymerized resin may cause an allergic reaction.

Carcinogenicity NTP IARC Monographs OSHA Regulated

none

Signs and Symptoms of Exposure Contact allergy.

Medical Conditions n.n.

Generally Aggravated by Exposure

Emergency and First Aid Procedures Wash with soap.

#### Section VII - Precautions for Safe Handling and Use

Steps to Be Taken Remove cured composite.

in Case Material is Released or Spilled Polymerized dental composite materials do not cause disturbances in sewage plants

Waste Disposal Method Garbage disposal

Precautions to Be Taken Store in a cold place.

in Handling and Storing

Avoid direct contact with skin or mucous membrane.

Other Pregautions Handle composite with spatula or syringe. Wear gloves.

The product should only be supplied to dentists or dental technicians or upon their

instructions.

#### Section VIII - Control Measures

Respiratory Protection (Specify Type) not required

Ventilation Local Exhaust - Special

Mechanical (General) - Other

Mechanical (General)

Protective Gloves X Eye Protection -

Work / Hygienic Practices Wash hands before breaks and after the end of a day's work.

Section IX - Information

Other Protective Clothing or Equipment

New MSDS



according to Regulation (EU) No. 1907/2006

**Cool Temp natural** 

Revision date: 10.06.2010 Print date: 10.06.2010 Page 1 of 4

# 1. Identification of the substance/preparation and of the company/undertaking

www.coltenewhaledent.com

#### Identification of the substance or preparation

Cool Temp natural

### Use of the substance/preparation

for dental use only

## Company/undertaking identification

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@coltenewhaledent.ch

### 2. Hazards identification

#### Classification

Internet:

Indications of danger: Irritant

R-phrases:

Irritating to eyes and skin.

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

### 3. Composition/information on ingredients

Chemical characterization (Mixture)

# Hazardous components

EC-No.	CAS-No.	Chemical name	Quantity	Classification
		UDMA	30 - 35 %	Xi R36/38
205-016-3	131-17-9	diallyl phthalate	10 - 15 %	Xn, N R22-50-53
221-950-4	3290-92-4	ТМРТМА	1 - 5 %	N R51-53

Full text of each relevant R phrase can be found in heading 16.

### 4. 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.

# 5. Fire-fighting measures

## Suitable extinguishing media

Water. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.



according to Regulation (EU) No. 1907/2006

# **Cool Temp natural**

Revision date: 10.06.2010 Print date: 10.06.2010 Page 2 of 4

#### Additional information

Extinguishing materials should be selected according to the surrounding area.

#### 6. Accidental release measures

#### Personal precautions

Avoid contact with skin and eyes.

#### **Environmental precautions**

Do not empty into drains or the aquatic environment.

# Methods for cleaning up/taking up

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

# 7. Handling and storage

### Handling

#### Advice on safe handling

Avoid contact with skin and eyes.

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

# Further information on handling

After use replace the closing cap immediately.

### Storage

### Further information on storage conditions

Substances sensitive to light.

Recommended storage temperature: 4 - 23 °C

### 8. Exposure controls/personal protection

#### **Exposure limit values**

#### **Exposure limits (EH40)**

CAS-No.	Chemical name	ml/m³	mg/m³	F/ml	Category	Origin
131-17-9	Diallyl phthalate	-	5		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

# **Exposure controls**

### Protective and hygiene measures

When using do not eat, drink or smoke.

### Hand protection

Single-use gloves. Suitable material: PVC (Polyvinyl chloride).

Roeko Glovyl - or comparable makes from other companies.

#### Eye protection

Framed glasses.

## Skin protection

Lab apron.



according to Regulation (EU) No. 1907/2006

Cool Temp natural

Revision date: 10.06.2010 Print date: 10.06.2010 Page 3 of 4

# 9. Physical and chemical properties

**General information** 

Physical state : Paste Colour : Off-white

Important health, safety and environmental information

Test method

Changes in the physical state

Density (at 23 °C):

Water solubility (at 23 °C):

Solubility in other solvents:

2.2 g/cm³

insoluble

Ethanol. (partially soluble)

# 10. Stability and reactivity

#### Conditions to avoid

Light.

UV-radiation/sunlight.

# 11. Toxicological information

# 12. Ecological information

# 13. Disposal considerations

### 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.

# 14. Transport information

# Land transport (ADR/RID)

UN number : ---

Warning plate

# Inland waterways transport

UN number: ---

Marine transport

UN number : ---

Air transport

UN/ID number : ---

# **Further Information**

Not a hazardous material with respect to these transportation regulations.

# 15. Regulatory information

# Labelling

Danger symbols : Xi - Irritant

#### Coltène/Whaledent AG

# Safety Data Sheet



according to Regulation (EU) No. 1907/2006

Cool Temp natural

Revision date : 10.06.2010		Print	date : 10.06.2010		Page 4 of	
	R phrases					
	36/38	Irritating to ey	es and skin.			
	52/53	Harmful to aq	uatic organisms, ma	ay cause long-term ac	lverse effects in the aquati	c environment.
	S phrases					

# National regulatory information

# 16. Other information

26

37

Full text of R	-phrases referred to under sections 2 and 3	
22	Harmful if swallowed	

Wear suitable gloves.

<b>ZZ</b>	Harmiul if Swallowed.
36/38	Irritating to eyes and skin.
50	Very toxic to aquatic organisms.
51	Toxic to aquatic organisms.
EOIEO	Harmful to aquatic arganisms m

52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

May cause long-term adverse effects in the aquatic environment.

#### **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.

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

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



according to Regulation (EC) No 1907/2006

### **Cool Temp natural**

Print date: 22.02.2018 Revision date: 27.04.2015 Page 1 of 6

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

### 1.1. Product identifier

Cool Temp natural

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

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

number:

#### **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

Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements: Causes skin irritation. Causes serious eve irritation.

Toxic to aquatic life with long lasting effects.

#### 2.2. Label elements

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

Signal word: Warning

Pictograms:





# **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

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



according to Regulation (EC) No 1907/2006

### **Cool Temp natural**

Revision date: 27.04.2015 Print date: 22.02.2018 Page 2 of 6

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						
	EC No	Index No	REACH No				
	Classification according to Regulati	on (EC) No. 1272/2008 [CLP]	•				
72869-86-4	UDMA						
	276-957-5						
	Skin Irrit. 2, Eye Irrit. 2; H315 H319						
131-17-9	diallyl phthalate						
	205-016-3	607-086-00-4					
	Acute Tox. 4, Aquatic Acute 1, Aqua						
3290-92-4	ТМРТМА		1 - < 5 %				
	221-950-4		01-2119542176-41				
	Aquatic Chronic 2; H411						

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**

#### 5.1. Extinguishing media

## Suitable extinguishing media

Water. Foam. Extinguishing powder. Carbon dioxide (CO2). 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**



according to Regulation (EC) No 1907/2006

# **Cool Temp natural**

Revision date: 27.04.2015 Print date: 22.02.2018 Page 3 of 6

### 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 - 23 °C

### **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

#### **Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m³	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/cm³ 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.



according to Regulation (EC) No 1907/2006

### **Cool Temp natural**

Revision date: 27.04.2015 Print date: 22.02.2018 Page 4 of 6

### 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 route	Dose		Species	Source	Method	
131-17-9	diallyl phthalate						
	oral	ATE mg/kg	500				
3290-92-4	ТМРТМА						
	oral	LD50 mg/kg	> 5000	Rat	literature value		
	dermal	LD50 mg/kg	> 3000	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	uatic toxicity Dose		[h]   [d]	Species	Source	Method
3290-92-4	ТМРТМА						
	Acute fish toxicity	LC50	2 mg/l	96 h	Oncorhynchus mykiss	literature value	
	Acute algae toxicity	ErC50 mg/l	0.177		Pseudokirchneriella subcapitata	literature value	
	Acute crustacea toxicity	EC50 mg/l	> 9.22	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.

### **SECTION 14: Transport information**



according to Regulation (EC) No 1907/2006

**Cool Temp natural** 

Revision date: 27.04.2015 Print date: 22.02.2018 Page 5 of 6

Land transport (ADR/RID)

14.1. UN number: UN 3082

14.2. UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(Diallyl phtalate)

14.3. Transport hazard class(es):914.4. Packing group:IIIHazard label:9Classification 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)

<u>14.1. UN number:</u> UN 3082

**14.2. UN** proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(Diallyl phtalate)

14.3. Transport hazard class(es):914.4. Packing group:IIIHazard label:9Special Provisions:274, 335Limited quantity:5 LExcepted quantity:E1

Air transport (ICAO-TI/IATA-DGR)

EmS:

**14.1. UN number:** UN 3082

**14.2. UN proper shipping name:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(Diallyl phtalate)

F-A, S-F

14.3. Transport hazard class(es):914.4. Packing group:IIIHazard label:9

Special Provisions:

Limited quantity Passenger:

Passenger LQ:

Excepted quantity:

A97 A158

30 kg G

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** 

-----

## **SECTION 16: Other information**



according to Regulation (EC) No 1907/2006

# **Cool Temp natural**

Revision date: 27.04.2015 Print date: 22.02.2018 Page 6 of 6

### Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
11440	Manutavia ta anuatia lifa with la

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.)