

according to Regulation (EC) No 1907/2006

**DuoTemp**

Revision date: 23.04.2015

Print date: 03.06.2015

Page 1 of 7

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

DuoTemp

**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:

Risk of serious damage to eyes.

Very 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:

Serious eye damage/eye irritation: Eye Dam. 1

Hazardous to the aquatic environment: Aquatic Acute 1

Hazardous to the aquatic environment: Aquatic Chronic 1

Hazard Statements:

Causes serious eye damage.

Very toxic to aquatic life with long lasting effects.

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

zinc sulfate monohydrate

Signal word:

Danger

Pictograms:

GHS05-GHS09

**Hazard statements**

H318

Causes serious eye damage.

H410

Very toxic to aquatic life with long lasting effects.

**Precautionary statements**

P273

Avoid release to the environment.

according to Regulation (EC) No 1907/2006

**DuoTemp**

Revision date: 23.04.2015

Print date: 03.06.2015

Page 2 of 7

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.

**Special labelling of certain mixtures**

EUH208 Contains Pfefferminzaroma. May produce an allergic reaction.

**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		
215-222-5	zinc oxide	
1314-13-2	N - Dangerous for the environment R50-53	30 - < 35 %
030-013-00-7	Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1 (M-Factor = 1); H400 H410	
276-957-5	UDMA	
72869-86-4	R52-53	15 - < 20 %
	Aquatic Chronic 3; H412	
231-793-3	zinc sulfate monohydrate	10 - < 15 %
7446-19-7	Xn - Harmful, Xi - Irritant, N - Dangerous for the environment R22-38-41-50-53	
	Acute Tox. 4, Eye Dam. 1, Aquatic Chronic 1 (M-Factor = 1); H302 H318 H410	
	Pfefferminzaroma	< 1 %
	Xi - Irritant R38-43-52-53	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, Aquatic Chronic 3; H315 H319 H317 H412	

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.

according to Regulation (EC) No 1907/2006

**DuoTemp**

Revision date: 23.04.2015

Print date: 03.06.2015

Page 3 of 7

**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**

Recommended storage temperature: 15 - 23 °C

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****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
Odour:	fruity

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

Density (at 23 °C):	2.5 g/cm <sup>3</sup>
Water solubility: (at 23 °C)	insoluble

according to Regulation (EC) No 1907/2006

**DuoTemp**

Revision date: 23.04.2015

Print date: 03.06.2015

Page 4 of 7

**Solubility in other solvents**

ketone. (partially soluble)

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

**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
1314-13-2	zinc oxide				
	oral	LD50	> 5000 mg/kg	Rat	IUCLID
72869-86-4	UDMA				
	oral	LD50	>2000 mg/kg	Rat	OECD 401
7446-19-7	zinc sulfate monohydrate				
	oral	LD50	574-2949 mg/kg	Rat	
	dermal	LD50	>2000 mg/kg	Rat	

**Irritation and corrosivity**

Causes serious eye damage.

**Sensitising effects**

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

**Additional information on tests**

No data available

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

CAS No	Chemical name					
	Aquatic toxicity	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
7446-19-7	zinc sulfate monohydrate					
	Acute crustacea toxicity	EC50	1.13 mg/l	48 h	Ceriodaphnia spec	US EPA 821-R-02-012

**12.2. Persistence and degradability**

according to Regulation (EC) No 1907/2006

**DuoTemp**

Revision date: 23.04.2015

Print date: 03.06.2015

Page 5 of 7

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

**Further information**

No data available

**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)**

<b>14.1. UN number:</b>	UN 3077
<b>14.2. UN proper shipping name:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., zinc oxide
<b>14.3. Transport hazard class(es):</b>	9
<b>14.4. Packing group:</b>	III
Hazard label:	9
Classification code:	M7
Limited quantity:	LQ27
Hazard No:	90

**Other applicable information (land transport)**

Special provisions: 274 335 601  
E1  
: 3  
E

**Marine transport (IMDG)**

<b>14.1. UN number:</b>	UN 3077
<b>14.2. UN proper shipping name:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., zinc oxide
<b>14.3. Transport hazard class(es):</b>	9
<b>14.4. Packing group:</b>	III
Hazard label:	9
Marine pollutant:	•
Limited quantity:	5 kg
EmS:	F-A, S-F

according to Regulation (EC) No 1907/2006

**DuoTemp**

Revision date: 23.04.2015

Print date: 03.06.2015

Page 6 of 7

**Other applicable information (marine transport)**

Special provisions: 274, 909, 944

**Air transport (ICAO)****14.1. UN number:** UN 3077**14.2. UN proper shipping name:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., zinc oxide**14.3. Transport hazard class(es):** 9**14.4. Packing group:** III

Hazard label: 9

Limited quantity Passenger: 30 kg G

IATA-packing instructions - Passenger: 911

IATA-max. quantity - Passenger: 400 kg

IATA-packing instructions - Cargo: 911

IATA-max. quantity - Cargo: 400 kg

**Other applicable information (air transport)**

E1

: Y911

400 kg

**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 R-phrases (Number and full text)**

- |    |   |
|----|---|
| 22 | Harmful if swallowed.   |
| 38 | Irritating to skin.   |
| 41 | Risk of serious damage to eyes.                                 |
| 43 | May cause sensitisation by skin contact.                        |
| 50 | Very 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)**

- |        |  |
|--------|--|
| H302   | Harmful if swallowed.  |
| H315   | Causes skin irritation.                                      |
| H317   | May cause an allergic skin reaction.                         |
| H318   | Causes serious eye damage.                                   |
| H319   | Causes serious eye irritation.                               |
| H400   | Very toxic to aquatic life.                                  |
| H410   | Very toxic to aquatic life with long lasting effects.        |
| H412   | Harmful to aquatic life with long lasting effects.           |
| EUH208 | Contains Pfefferminzaroma. May produce an allergic reaction. |

**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.

according to Regulation (EC) No 1907/2006

**DuoTemp**

Revision date: 23.04.2015

Print date: 03.06.2015

Page 7 of 7

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