# Safety Data Sheet



according to Regulation (EC) No 1907/2006

# DuoTemp

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

number:

#### **SECTION 2: Hazards identification**

# 2.1. Classification of the substance or mixture

# Regulation (EC) No. 1272/2008

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

# Regulation (EC) No. 1272/2008

# Hazard components for labelling

zinc sulfate monohydrate Danger

Signal word:

Pictograms:



# 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.
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

Contains Pfefferminzaroma. May produce an allergic reaction. EUH208

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# 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				
	EC No	Index No	REACH No		
	Classification according to Regulat	tion (EC) No. 1272/2008 [C	LP]		
1314-13-2	zinc oxide				
	215-222-5	030-013-00-7			
	Aquatic Acute 1, Aquatic Chronic 1	; H400 H410			
72869-86-4	I6-4 UDMA		15 - < 20 %		
	276-957-5				
	Aquatic Chronic 3; H412		-		
7446-19-7	zinc sulfate monohydrate		10 - < 15 %		
	231-793-3				
	Acute Tox. 4, Eye Dam. 1, Aquatic	Chronic 1; H302 H318 H4	0		
	Pfefferminzaroma			< 1 %	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens.	1, Aquatic Chronic 3; H31	5 H319 H317 H412		

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.

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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 (eq. 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 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

#### Changes in the physical state

Density (at 23 °C): Water solubility: (at 23 °C) 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.

#### Test method

insoluble

2.5 g/cm<sup>3</sup>



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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
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 mg/kg	574-2949	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 Dose [h]   [d] Species Source				Source	
72869-86-4	UDMA					
	Acute fish toxicity	LC50	10.1 mg/l		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

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



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#### 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)

<u>14.1. UN number:</u>	UN 3077	
14.2. UN proper shipping name:	ENVIRONMENTALL oxide	Y HAZARDOUS SUBSTANCE, SOLID, N.O.S., zinc
14.3. Transport hazard class(es):	9	
14.4. Packing group:	III	
Hazard label:	9	
Classification code:	M7	
Limited quantity:	LQ27	
Hazard No:	90	
Other applicable information (land transp Special provisions: 274 335 601 E1 : 3 E	ort)	
Marine transport (IMDG)		
<u>14.1. UN number:</u>	UN 3077	
14.2. UN proper shipping name:	ENVIRONMENTALL oxide	Y HAZARDOUS SUBSTANCE, SOLID, N.O.S., zinc
14.3. Transport hazard class(es):	9	
14.4. Packing group:	III	
Hazard label:	9	
Marine pollutant:	•	
Limited quantity:	5 kg	
EmS:	F-A, S-F	
Other applicable information (marine tran Special provisions: 274, 909, 944	isport)	
Air transport (ICAO)		
<u>14.1. UN number:</u>	UN 3077	
14.2. UN proper shipping name:	ENVIRONMENTALL oxide	Y HAZARDOUS SUBSTANCE, SOLID, N.O.S., zinc
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



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IATA-max. quantity - Cargo:	400 kg	
Other applicable information (air transport) E1 : Y911 400 kg		
SECTION 15: Regulatory information		

#### National regulatory information

Additional information

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# **SECTION 16: Other information**

# Relevant H and EUH statements (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.

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