SAFETY DATA SHEETS

This SDS packet was issued with item:

077186802

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).

077186810



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

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

Signal word: Danger

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

EUH208 Contains Pfefferminzaroma. May produce an allergic reaction.



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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 Regulation (EC) No. 1272/2008 [CLP]					
1314-13-2	zinc oxide					
	215-222-5	030-013-00-7				
	Aquatic Acute 1, Aquatic Chronic 1;	Aquatic Acute 1, Aquatic Chronic 1; H400 H410				
72869-86-4	UDMA					
	276-957-5					
	Aquatic Chronic 3; H412					
7446-19-7	zinc sulfate monohydrate					
	231-793-3					
	Acute Tox. 4, Eye Dam. 1, Aquatic Chronic 1; H302 H318 H410					
	Pfefferminzaroma					
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, Aquatic Chronic 3; H315 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

Test method

Changes in the physical state

Density (at 23 °C):

Water solubility:

insoluble

(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.



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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
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)

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):914.4. Packing group:IIIHazard label:9Classification code:M7Limited quantity:LQ27Hazard No:90

Other applicable information (land transport)

Special provisions: 274 335 601

E1 : 3 E

Marine transport (IMDG)

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):914.4. Packing group:IIIHazard label:9Marine pollutant:•Limited quantity:5 kgEmS:F-A, S-F

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):914.4. Packing group:IIIHazard label:9Limited quantity Passenger:30 kg G

IATA-packing instructions - Passenger:911IATA-max. quantity - Passenger:400 kgIATA-packing instructions - Cargo:911



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IATA-max. quantity - Cargo: 400 kg

Other applicable information (air transport)

E1 : Y911 400 ka

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)

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.)