

according to Regulation (EC) No 1907/2006

Coltosol F

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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: COLTENE/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 number: +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

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 sulphate (hydrous) (mono-, hexa- and hepta hydrate)

Signal word: Danger**Pictograms:****Hazard statements**

H318 Causes serious eye damage.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P202 Do not handle until all safety precautions have been read and understood.

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.

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Special labelling of certain mixtures

EUH208 Contains mint aroma. 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**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
1314-13-2	zinc oxide			30 - < 35 %
	215-222-5	030-013-00-7		
	Aquatic Acute 1, Aquatic Chronic 1; H400 H410			
7446-19-7	zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate)			10 - < 15 %
	231-793-3	030-006-00-9		
	Acute Tox. 4, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H302 H318 H400 H410			
n.a.	mint aroma			< 0, 2 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, Aquatic Chronic 3; H315 H319 H317 H412			
7681-49-4	sodium fluoride			< 0.1 %
	231-667-8	009-004-00-7		
	Acute Tox. 3, Eye Irrit. 2, Skin Irrit. 2; H301 H319 H315 EUH032			

Full text of H and EUH statements: see section 16.

Further Information

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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.

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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.
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):	2.4 g/cm ³
Water solubility: (at 23 °C)	insoluble

Solubility in other solvents

ketone. (partially soluble)

SECTION 10: Stability and reactivity

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10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute toxicity**

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
1314-13-2	zinc oxide				
	oral	LD50 > 5000 mg/kg	Rat	IUCLID	
7446-19-7	zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate)				
	oral	LD50 574-2949 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
7681-49-4	sodium fluoride				
	oral	LD50 52 mg/kg	Rat	RTECS	

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	Method
7446-19-7	zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate)					
	Acute crustacea toxicity	EC50 1.13 mg/l	48 h	Ceriodaphnia spec	US EPA 821-R-02-012	
7681-49-4	sodium fluoride					
	Acute fish toxicity	LC50 925 mg/l	96 h	Gambusia affinis		
	Acute algae toxicity	ErC50 850 mg/l	72 h	Desmodesmus subspicatus		
	Acute crustacea toxicity	EC50 338 mg/l	48 h	Daphnia magna	IUCLID	

Further information

No data available

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Advice on disposal**

Dispose of waste according to applicable legislation.

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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):	9
14.4. Packing group:	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)

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
Marine pollutant:	•
Limited quantity:	5 kg
EmS:	F-A, S-F

Other applicable information (marine transport)

Special provisions: 274, 909, 944

Air transport (ICAO-TI/IATA-DGR)

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**

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National regulatory information**Additional information**

SECTION 16: Other information**Changes**

* Data changed compared with the previous version

Abbreviations and acronymsADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

n.a.: not applicable

Relevant H and EUH statements (number and full text)

H301	Toxic if swallowed.
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.
EUH032	Contact with acids liberates very toxic gas.
EUH208	Contains mint aroma. 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.)