

according to Regulation (EC) No 1907/2006

**Coltosol F**

Revision date: 22.04.2015

Print date: 08.03.2018

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

Coltosol F

**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 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.

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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	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
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 sulfate monohydrate			10 - < 15 %
	231-793-3			
	Acute Tox. 4, Eye Dam. 1, Aquatic Chronic 1; H302 H318 H410			
	mint aroma			< 1 %
	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.

**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.**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**

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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 <sup>3</sup>
Water solubility: (at 23 °C)	insoluble

**Solubility in other solvents**

ketone. (partially soluble)

**SECTION 10: Stability and reactivity****10.2. Chemical stability**

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

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**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 sulfate monohydrate				
	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 sulfate monohydrate					
	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**

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**

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**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

**Other applicable information (marine transport)**

Special provisions: 274, 909, 944

**Air transport (ICAO-TI/IATA-DGR)**

<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
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**

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**SECTION 16: Other information****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.)*