Safety Data Sheet



according to Regulation (EC) No 1907/2006

Temposil 2

Revision date: 28.04.2015

Print date: 17.05.2016

Page 1 of 5

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Temposil 2

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: Hazardous to the aquatic environment: Aquatic Acute 1 Hazardous to the aquatic environment: Aquatic Chronic 1 Hazard Statements: Very toxic to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Signal word: Warning

Pictograms:



Hazard statements

H410

Very toxic to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment. P391 Collect spillage.

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



according to Regulation (EC) No 1907/2006

Temposil 2

Revision date: 28.04.2015

Print date: 17.05.2016

Page 2 of 5

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			65 - < 70 %
	215-222-5	030-013-00-7		
	Aquatic Acute 1, Aquatic Chronic 1; H400 H410			

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.

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

Safety Data Sheet



according to Regulation (EC) No 1907/2006

Temposil 2			
Revision date: 28.04.2015	Print date: 17.05.2016		Page 3 of 5
8.1. Control parameters			
8.2. Exposure controls			
Protective and hygiene measures When using do not eat, drink or			
Eye/face protection Framed glasses.			
Hand protection Single-use gloves.			
Skin protection Lab apron.			
SECTION 9: Physical and chemic	al properties		
9.1. Information on basic physical ar	nd chemical properties		
Physical state:	Paste		
Colour:	off-white		
		Test method	
Changes in the physical state			
Density (at 23 °C):		2.3 g/cm ³	
Water solubility: (at 23 °C)		insoluble	
Solubility in other solvents ketone. (partially soluble)			
SECTION 10: Stability and reactivity			
10.6. Hazardous decomposition proc Hydrogen.	lucts		
SECTION 11: Toxicological information			
11.1. Information on toxicological eff	fects		

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

Irritation and corrosivity

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

Sensitising effects

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

Additional information on tests

No data available

SECTION 12: Ecological information

Further information

No data available



zinc

zinc

according to Regulation (EC) No 1907/2006

Temposi	I 2
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Revision date: 28.04.2015

Print date: 17.05.2016

Page 4 of 5

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal Can be burnt together with househo waste disposal companies and with	ld waste in compliance with official regulations in contact with approved 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:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.,
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 tra Special provisions: 274 335 601 E1 : 3 E	nsport)
Marine transport (IMDG)	
<u>14.1. UN number:</u>	UN 3077
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., a 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 the Special provisions: 274, 909, 944	transport)
Air transport (ICAO)	
·	

<u>14.1. UN number:</u>	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



according to Regulation (EC) No 1907/2006

Temposil 2

Revision date: 28.04.2015

Print date: 17.05.2016

Page 5 of 5

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

H410

SECTION 16: Other information

Relevant H and EUH statements (number and full text) H400

Very toxic to aquatic life.

Very toxic to aquatic life with long lasting effects.

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.)