

according to Regulation (EC) No 1907/2006

Temposil 2

Revision date: 28.04.2015

Print date: 04.05.2015

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

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Directive 67/548/EEC or 1999/45/EC**

Indications of danger: N - Dangerous for the environment

R phrases:

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

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

Signal word: Warning

Pictograms: GHS09

**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.

according to Regulation (EC) No 1907/2006

Temposil 2

Revision date: 28.04.2015

Print date: 04.05.2015

Page 2 of 5

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Hazardous components**

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
215-222-5	zinc oxide	
1314-13-2	N - Dangerous for the environment R50-53	65 - < 70 %
030-013-00-7	Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1 (M-Factor = 1); H400 H410	

Full text of R-, H- and EUH-phrases: 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.

Restricted to professional users. Keep out of the reach of children.

Observe instructions for use.

Further information on handling

After use replace the closing cap immediately.

according to Regulation (EC) No 1907/2006

Temposil 2

Revision date: 28.04.2015

Print date: 04.05.2015

Page 3 of 5

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

Test method**Changes in the physical state**

Density (at 23 °C):

2.3 g/cm³Water solubility:
(at 23 °C)

insoluble

Solubility in other solvents

ketone. (partially soluble)

SECTION 10: Stability and reactivity**10.6. Hazardous decomposition products**

Hydrogen.

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 routes	Method	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.

according to Regulation (EC) No 1907/2006

Temposil 2

Revision date: 28.04.2015

Print date: 04.05.2015

Page 4 of 5

Additional information on tests

No data available

SECTION 12: Ecological information**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):	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)

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

according to Regulation (EC) No 1907/2006

Temposil 2

Revision date: 28.04.2015

Print date: 04.05.2015

Page 5 of 5

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****National regulatory information****Additional information**

SECTION 16: Other information**Relevant R-phrases (Number and full text)**

- | | |
|----|---|
| 50 | Very toxic to aquatic organisms. |
| 53 | May cause long-term adverse effects in the aquatic environment. |

Relevant H- and EUH-phrases (Number and full text)

- | | |
|------|---|
| H400 | Very toxic to aquatic life. |
| H410 | 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.)