

according to Regulation (EC) No 1907/2006

**Temposil 2**

Revision date: 28.04.2015

Print date: 30.04.2015

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: 30.04.2015

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 (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**

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: 30.04.2015

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**

Water solubility:

insoluble

(at 23 °C)

**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: 30.04.2015

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)**

<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)**

<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

according to Regulation (EC) No 1907/2006

**Temposil 2**

Revision date: 28.04.2015

Print date: 30.04.2015

Page 5 of 5

<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**

-----

**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.)*