

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

077244932

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

077244940

according to Regulation (EC) No 1907/2006

**Temposil 2**

Revision date: 12.07.2012

Print date: 23.04.2013

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**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

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture**

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.

**2.2. Label elements**

Danger symbols: N - Dangerous for the environment



N - Dangerous for the environment

**R phrases**

50/53

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

**S phrases**

61

Avoid release to the environment. Refer to special instructions / Safety data sheets.

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

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
215-222-5	zinc oxide	65 - 70 %
1314-13-2	N - Dangerous for the environment R50-53	
030-013-00-7	Aquatic Acute 1, Aquatic Chronic 1; H400 H410	

Full text of R and H phrases: see Section 16.

according to Regulation (EC) No 1907/2006

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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 (CO<sub>2</sub>). Sand.**Additional information**

Extinguishing materials should be selected according to the surrounding area.

**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 empty into drains or the aquatic environment.

**6.3. Methods and material for containment and cleaning up**

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated area 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.

**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.

**Hand protection**

Single-use gloves.

**Eye protection**

Framed glasses.

according to Regulation (EC) No 1907/2006

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**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****Flammability**

Water solubility: insoluble  
 (at 23 °C)

ISO 10156

**Solubility in other solvents**

ketone.

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

Hydrogen.

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

CAS No	Chemical name				
	Exposure routes	Method	Dose	Species	Source
1314-13-2	zinc oxide				
	oral	LD50 mg/kg	> 5000	Rat	IUCLID

**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:** 3077**14.2. UN proper shipping name:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., zinc oxide

according to Regulation (EC) No 1907/2006

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**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:** 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)**

**UN/ID number:** 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****National regulatory information****SECTION 16: Other information****Full text of R phrases referred to under Sections 2 and 3**

50 Very toxic to aquatic organisms.

according to Regulation (EC) No 1907/2006

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50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

53 May cause long-term adverse effects in the aquatic environment.

**Full text of H statements referred to under Sections 2 and 3**

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.

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*

according to Regulation (EC) No 1907/2006

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Revision date: 28.04.2015

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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:	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 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:

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

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**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 (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.

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**



according to Regulation (EC) No 1907/2006

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**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/cm<sup>3</sup>  
 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 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

according to Regulation (EC) No 1907/2006

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**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
<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

according to Regulation (EC) No 1907/2006

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**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)**

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.)*