

according to Regulation (EC) No 1907/2006

PSI Base

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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

Further Information

Only supplied to dentists and dental laboratories or upon their instructions

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

This mixture is classified as not hazardous according to Regulation (EC) 1272/2008 [GHS].
The preparation is not dangerous in the sense of Directive 1999/45/EC.
Preparation/mixture without hazards for human health or environment

2.2. Label elements**Hazardous components which must be listed on the label**

According to EC directive 1999/45/EC or annex VI of directive 67/548/EEC the preparation does not have to be labelled.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

Polymer preparations and compounds

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

No special measures are necessary.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**Water. Foam. Extinguishing powder. Carbon dioxide (CO₂). Sand.

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Additional information

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures**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**

No special precautionary measures are necessary.

Observe instructions for use.

7.2. Conditions for safe storage, including any incompatibilities**Further information on storage conditions**

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

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.

Unsuitable material: NR (Natural rubber (Caoutchouc), Natural latex).

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:

Paste

Colour:

Test method**Changes in the physical state**

Initial boiling point and boiling range:

>150 °C

Water solubility:

insoluble

(at 23 °C)

Solubility in other solvents

ketone.

SECTION 10: Stability and reactivity**Further information**

No special measures are necessary.

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

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Acute toxicity

LD50: >2000 mg/kg (Rat)

The statement is derived from products of similar composition.

Irritation and corrosivity

Irritant effect on the skin: (Rabbit)

Not an irritant.

The statement is derived from products of similar composition.

Sensitising effects

Guinea-pig.

no danger of sensitization.

The statement is derived from products of similar composition.

SECTION 12: Ecological information**Further information**

No special environmental measures are necessary.

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**Other applicable information**

Not a hazardous material with respect to these transportation regulations.

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**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.)

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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**

Activator.

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
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e-mail: info.ch@coltene.com
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msds@coltene.com

Further Information

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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: Xn - Harmful

R phrases:

Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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

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

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Specific target organ toxicity - repeated exposure: STOT RE 2

Hazardous to the aquatic environment: Aquatic Chronic 4

Hazard Statements:

Causes skin irritation.

Causes serious eye irritation.

May cause damage to organs through prolonged or repeated exposure.

May cause long lasting harmful effects to aquatic life.

2.2. Label elements**Hazardous components which must be listed on the label**

Alkyl silicates

Signal word:

Warning

Pictograms:

GHS07-GHS08



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Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H413	May cause long lasting harmful effects to aquatic life.

Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
P314	Get medical advice/attention if you feel unwell.
P273	Avoid release to the environment.

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**

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		
	Alkyl silicates	15 - < 20 %
	Xn - Harmful, Xi - Irritant R10-20-36/37/38-48/22-53	
	Flam. Liq. 3, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, STOT RE 2, Aquatic Chronic 4; H226 H332 H315 H319 H335 H373 H413	
246-325-3	Diocetyl tin dicarboxylate	5 - < 10 %
24577-34-2	Xn - Harmful R48/22-53	
	STOT RE 2, Aquatic Chronic 4; H373 H413	

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**

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Suitable extinguishing mediaWater. Foam. Extinguishing powder. Carbon dioxide (CO₂). Sand.**Additional information**

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures**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.

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**

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

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:	green
Odour:	characteristic

Test method**Changes in the physical state**

Initial boiling point and boiling range:	>150 °C
Density (at 23 °C):	1.0 g/cm ³
Water solubility: (at 23 °C)	insoluble

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Solubility in other solvents

ketone.

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

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

10.4. Conditions to avoid

Air, humid.

Further information

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

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

LD50: >2000 mg/kg (Rat)

The statement is derived from products of similar composition.

CAS No	Chemical name				
	Exposure routes	Method	Dose	Species	Source
	Alkyl silicates				
	inhalative vapour	ATE	11 mg/l		
	inhalative aerosol	ATE	1.5 mg/l		
24577-34-2	Dioctyltin dicarboxylate				
	oral	LD50	2764 mg/kg	Rat	
	dermal	LD50	2764 mg/kg	Rabbit	

Irritation and corrosivity

Causes serious eye irritation.

Irritant effect on the skin: (Rabbit)

Not an irritant.

The statement is derived from products of similar composition.

Sensitising effects

Guinea-pig.

no danger of sensitization.

The statement is derived from products of similar composition.

Severe effects after repeated or prolonged exposure

May cause damage to organs through prolonged or repeated exposure.

SECTION 12: Ecological information**12.1. Toxicity**

CAS No	Chemical name				
	Aquatic toxicity	Method	Dose	[h] [d]	Species
24577-34-2	Dioctyltin dicarboxylate				
	Acute fish toxicity	LC50	22.8 mg/l	96 h	
	Acute crustacea toxicity	EC50	12.2 mg/l	48 h	Daphnia magna

Further information

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

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Do not allow uncontrolled leakage of product into the environment.

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:** -----**Marine transport (IMDG)****14.1. UN number:** -----**Air transport (ICAO)****14.1. UN number:** -----**Other applicable information**

Not a hazardous material with respect to these transportation regulations.

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)**

- | | |
|----------|---|
| 10 | Flammable. |
| 20 | Harmful by inhalation. |
| 36/37/38 | Irritating to eyes, respiratory system and skin. |
| 48/22 | Harmful: danger of serious damage to health by prolonged exposure if swallowed. |
| 53 | May cause long-term adverse effects in the aquatic environment. |

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

- | | |
|------|--|
| H226 | Flammable liquid and vapour. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H332 | Harmful if inhaled. |
| H335 | May cause respiratory irritation. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H413 | May cause long lasting harmful effects to aquatic life. |

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.)