

## **SAFETY DATA SHEETS**

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

077246176

**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).**

077245103 077245111 077245202 077245210 077245285 077245293 077245467 077246119 077246127 077246135  
077246143 077246150 077246168 077246184 077246382 077246390 077246408 077246416 077246424 077246432  
077246440 077246499 077246507 077246515 077246523 077246531 077246549 077246556

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**1. Identification of the substance/preparation and of the company/undertaking****Identification of the substance or preparation**

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**Use of the substance/preparation**

for dental use only

**Company/undertaking identification**

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@coltenewhaledent.ch  
Internet : www.coltenewhaledent.com

**2. Hazards identification****Classification**

Indications of danger : Irritant

R-phrases :

Irritating to eyes, respiratory system and skin.

May cause sensitization by skin contact.

**3. Composition/information on ingredients****Chemical characterization ( Mixture )****Hazardous components**

EC-No.	CAS-No.	Chemical name	Quantity	Classification
216-367-7	1565-94-2	BISGMA	10 - 15 %	Xi R36/37/38
203-652-6	109-16-0	TEGDMA	5 - 10 %	Xi R36/37/38-43

Full text of each relevant R phrase can be found in heading 16.

**4. 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.

**5. Fire-fighting measures****Suitable extinguishing media**

Water. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.

**Additional information**

Extinguishing materials should be selected according to the surrounding area.

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**6. Accidental release measures****Personal precautions**

Avoid contact with skin and eyes.

**Environmental precautions**

Do not empty into drains or the aquatic environment.

**Methods for cleaning up/taking up**

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

**7. Handling and storage****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.

**Storage****Further information on storage conditions**

Substances sensitive to light.

Recommended storage temperature: 4 - 23 °C

**8. Exposure controls/personal protection****Exposure limit values****Exposure controls****Protective and hygiene measures**

When using do not eat, drink or smoke.

**Hand protection**

Single-use gloves. Suitable material: PVC (Polyvinyl chloride).

Roeko Glovyl - or comparable makes from other companies.

**Eye protection**

Framed glasses.

**Skin protection**

Lab apron.

**9. Physical and chemical properties****General information**

Physical state : Paste  
Colour : off-white

**Important health, safety and environmental information**

Test method

**Changes in the physical state**

Density (at 23 °C) : 1.8 g/cm<sup>3</sup>  
Water solubility (at 23 °C) : insoluble

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Solubility in other solvents : Ethanol. (partially soluble)

**10. Stability and reactivity****Conditions to avoid**Light.  
UV-radiation/sunlight.**11. Toxicological information****Sensitising effects**

May cause sensitization in susceptible people.

**12. Ecological information****Further information**

According to the criteria of the EC-classification and labelling "dangerous for the environment" (93/21/EEC) the material/product is not to be classified as dangerous to the environment.

**13. Disposal considerations****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.

**14. Transport information****Land transport (ADR/RID)**UN number : ---  
Warning plate**Inland waterways transport**

UN number : ---

**Marine transport**

UN number : ---

**Air transport**

UN/ID number : ---

**Further Information**

Not a hazardous material with respect to these transportation regulations.

**15. Regulatory information****Labelling**

Danger symbols : Xi - Irritant

**Hazardous component(s) to be indicated on label**  
TEGDMA**R phrases**36/37/38 Irritating to eyes, respiratory system and skin.  
43 May cause sensitization by skin contact.

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**S phrases**

- 24 Avoid contact with skin.  
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
37 Wear suitable gloves.

**National regulatory information****16. Other information****Full text of R-phrases referred to under sections 2 and 3**

- 36/37/38 Irritating to eyes, respiratory system and skin.  
43 May cause sensitization by skin contact.

**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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**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:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory or skin sensitisation: Skin Sens. 1

Specific target organ toxicity - single exposure: STOT SE 3

Hazard Statements:

Causes skin irritation.

May cause an allergic skin reaction.

Causes serious eye irritation.

May cause respiratory irritation.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Hazard components for labelling**

TEGDMA

**Signal word:** Warning**Pictograms:****Hazard statements**

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

**Precautionary statements**

P280	Wear protective gloves/protective clothing/eye protection/face protection.
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according to Regulation (EC) No 1907/2006

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P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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.

**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**

CAS No	Chemical name	Quantity
	EC No	
	Index No	
	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
1565-94-2	BISGMA	10 - < 15 %
	216-367-7	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335	
109-16-0	TEGDMA	5 - < 10 %
	203-652-6	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335	

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.

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**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**

Substances sensitive to light.  
Recommended storage temperature: 4 - 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):	1.8 g/cm <sup>3</sup>
Water solubility: (at 23 °C)	insoluble

**Solubility in other solvents**

Ethanol. (partially soluble)

**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**

Light.  
UV-radiation/sunlight.



according to Regulation (EC) No 1907/2006

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**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
109-16-0	TEGDMA			
	oral	LD50 10837 mg/kg	Rat	literature value

**Irritation and corrosivity**

Causes skin irritation.

Causes serious eye irritation.

**Sensitising effects**

May cause an allergic skin reaction. (TEGDMA)

**STOT-single exposure**

May cause respiratory irritation.

**SECTION 12: Ecological information****12.3. Bioaccumulative potential****Partition coefficient n-octanol/water**

CAS No	Chemical name	Log Pow
1565-94-2	BISGMA	4.94
109-16-0	TEGDMA	1.88

**Further information**

According to the criteria of the EC-classification and labelling "dangerous for the environment" (93/21/EEC) the material/product is not to be classified as dangerous to 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:** ---**Inland waterways transport (ADN)****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.

according to Regulation (EC) No 1907/2006

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**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)**

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

**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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