

according to Regulation (EC) No 1907/2006

**Synergy Nano Formula**

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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

**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: Xi - Irritant

R phrases:

May cause sensitisation by skin contact.

**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

Respiratory/skin sensitization: Skin Sens. 1

Hazard Statements:

Causes skin irritation.

May cause an allergic skin reaction.

Causes serious eye irritation.

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

TEGDMA

Signal word: Warning

Pictograms: GHS07

**Hazard statements**

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

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#### Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
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.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: 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

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		
216-367-7	BISGMA	5 - < 10 %
1565-94-2	Xi - Irritant R36/37/38	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335	
203-652-6	TEGDMA	5 - < 10 %
109-16-0	Xi - Irritant R36/37/38-43	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335	

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.

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**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.

**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): 2.2 g/cm<sup>3</sup>Water solubility: insoluble  
(at 23 °C)**Solubility in other solvents**

Ethanol. (partially soluble)

**SECTION 10: Stability and reactivity****10.4. Conditions to avoid**

Light.  
UV-radiation/sunlight.

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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 routes	Method	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)

## 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.

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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 R-phrases (Number and full text)**

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

**Relevant H- and EUH-phrases (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.

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