

according to Regulation (EC) No 1907/2006

**Brilliant EverGlow**

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Print date: 20.02.2018

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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:	COLTENE/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:

Respiratory or skin sensitisation: Skin Sens. 1

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

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

TEGDMA

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

H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.

**Precautionary statements**

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P262	Do not get in eyes, on skin, or on clothing.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P273	Avoid release to the environment.

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**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]			
109-16-0	TEGDMA			1 - < 5 %
	203-652-6			
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335			
1565-94-2	BISGMA			1 - < 5 %
	216-367-7			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
1314-13-2	zinc oxide coated			< 1.5 %
	215-222-5	030-013-00-7		
	Skin Irrit. 3, Eye Irrit. 2B, Aquatic Acute 1, Aquatic Chronic 1; H316 H320 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.

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

**Solubility in other solvents**

Ethanol. (partially soluble)

**9.2. Other information**

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**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.

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UV-radiation/sunlight.

## 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	Method	
109-16-0	TEGDMA					
	oral	LD50 mg/kg	10837	Rat	literature value	
1314-13-2	zinc oxide coated					
	oral	LD50 mg/kg	7950	Mouse.	literature information	

#### Irritation and corrosivity

Based on available data, the classification criteria are not met.

#### 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
109-16-0	TEGDMA	1.88
1565-94-2	BISGMA	4.94

### 12.5. Results of PBT and vPvB assessment

not applicable

## 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-TI/IATA-DGR)

**14.1. UN number:** ---

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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**

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**SECTION 16: Other information****Abbreviations and acronyms**

ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service  
LC50: Lethal concentration, 50%  
LD50: Lethal dose, 50%

**Relevant H and EUH statements (number and full text)**

H315	Causes skin irritation.
H316	Causes mild skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H320	Causes eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful 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.)*