

according to Regulation (EC) No 1907/2006

### **Brilliant EverGlow**

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## SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

**Brilliant EverGlow** 

## 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** +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

number:

#### **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.

## Additional advice on labelling

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact



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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					
	EC No	Index No	REACH No			
	Classification according to Regulati	on (EC) No. 1272/2008 [CLP]	•			
109-16-0	TEGDMA					
	203-652-6					
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens.	rin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335				
1565-94-2	BISGMA					
	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 (CO2). 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**



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# 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):

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.

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 route	Dose		Species	Source					
109-16-0	TEGDMA									
	oral	LD50	10837 mg/kg	Rat	literature value					
1314-13-2	zinc oxide coated									
	oral	LD50	7950 mg/kg	Mouse.	literature infomation					

### 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)

<u>14.1. UN number:</u> ---

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number:</u> ---

# 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**

#### 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.)



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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

## 1.1. Product identifier

One Coat 7 Universal

#### 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 +41 (71) 75 75 300 Telephone: 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** +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

number:

# **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

# Regulation (EC) No. 1272/2008

Hazard categories:

Flammable liquid: Flam. Liq. 3 Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2 Respiratory or skin sensitisation: Skin Sens. 1

Hazard Statements:

Flammable liquid and vapour.

Causes skin irritation.

May cause an allergic skin reaction. Causes serious eye irritation.

### 2.2. Label elements

# Regulation (EC) No. 1272/2008

#### Hazard components for labelling

2-hydroxyethyl methacrylate

Signal word: Warning

Pictograms:





# **Hazard statements**

H226 Flammable liquid and vapour.

H315 Causes skin irritation.

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

## **Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection.



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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.

P333+P313 If skin irritation or rash 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**

CAS No	Chemical name					
	EC No	Index No	REACH No			
	Classification according to Regulat	ion (EC) No. 1272/2008 [CLP]	•			
64-17-5	ethanol, ethyl alcohol					
	200-578-6	603-002-00-5				
	Flam. Liq. 2; H225					
72869-86-4	Urethane dimethacrylate					
	276-957-5					
	Aquatic Chronic 3; H412					
868-77-9	2-hydroxyethyl methacrylate			5 - < 10 %		
	212-782-2	607-124-00-X				
	Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1; H319 H315 H317					

Full text of H and EUH statements: see section 16.

### **SECTION 4: First aid measures**

## 4.1. Description of first aid measures

## After inhalation

Provide fresh air.

### 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 advice.

## **SECTION 5: Firefighting measures**

### 5.1. Extinguishing media

#### Suitable extinguishing media

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

#### **Additional information**

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

### **SECTION 6: Accidental release measures**



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### 6.1. Personal precautions, protective equipment and emergency procedures

Remove all sources of ignition. Provide adequate ventilation. Remove persons to safety.

### 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.

#### Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking.

#### Further information on handling

After use replace the closing cap immediately.

## 7.2. Conditions for safe storage, including any incompatibilities

### Requirements for storage rooms and vessels

Keep container tightly closed and in a well-ventilated place.

# Further information on storage conditions

Recommended storage temperature: 4 - 8 °C

# **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

## **Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

## 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.

### Respiratory protection

Provide adequate ventilation.

## **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state: liquid
Colour: light yellow



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Odour: characteristic

**Test method** 

Changes in the physical state

Flash point: 28 °C

Density: 1.0 g/cm³

Water solubility: partially soluble

Solubility in other solvents

Ethanol.

# **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

heat.

## 10.5. Incompatible materials

Oxidizing agents.

# **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			
64-17-5	ethanol, ethyl alcohol								
	oral	LD50 mg/kg	6200	Rat	IUCLID				
	inhalative (4 h) vapour	LC50	95,6 mg/l	Rat	RTECS				
72869-86-4	Urethane dimethacrylate								
	oral	LD50 mg/kg	>2000	Rat		OECD 401			
868-77-9	2-hydroxyethyl methacrylate								
	oral	LD50 mg/kg	5050	Rat					

### Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

# Sensitising effects

May cause an allergic skin reaction. (2-hydroxyethyl methacrylate)

# **SECTION 12: Ecological information**

# 12.1. Toxicity



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CAS No	Chemical name								
	Aquatic toxicity	Dose		[h]   [d]	Species	Source	Method		
64-17-5	ethanol, ethyl alcohol	ethanol, ethyl alcohol							
	Acute crustacea toxicity	Acute crustacea toxicity EC50 9268 - 48 h Daphnia magna IUCLID							
72869-86-4	Urethane dimethacrylate	Urethane dimethacrylate							
	Acute fish toxicity	LC50 mg/l	10.1		Brachydanio rerio (zebra-fish)		OECD 203		
868-77-9	2-hydroxyethyl methacryla	2-hydroxyethyl methacrylate							
	Acute fish toxicity	Acute fish toxicity LC50 227 mg/l 96 h Pimephales promelas							

## 12.2. Persistence and degradability

CAS No	Chemical name							
	Method	Value	d	Source				
	Evaluation							
72869-86-4	Urethane dimethacrylate							
	OECD 301 F	22%	28					
	Product is not easily biodegradable.							

### 12.3. Bioaccumulative potential

#### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
64-17-5	ethanol, ethyl alcohol	-0,31
72869-86-4	Urethane dimethacrylate	3.39
868-77-9	2-hydroxyethyl methacrylate	0,47

### **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:** UN 1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es):314.4. Packing group:IIHazard label:3Classification code:F1Limited quantity:LQ4Hazard No:33

## Other applicable information (land transport)

Special provisions: 274

E3



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: 1 D/E

Special provisions: 274 601 640C

E2 : 2

Special provisions: 640C Special provisions: 144 601

Marine transport (IMDG)

**14.1. UN number:** UN 1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

 14.3. Transport hazard class(es):
 3

 14.4. Packing group:
 II

 Hazard label:
 3

 Limited quantity:
 3 L

 EmS:
 F-E, S-D

Other applicable information (marine transport)

Special provisions: 274, 330, 944 Special provisions: 944 Special provisions: 144, 330

Air transport (ICAO-TI/IATA-DGR)

**14.1. UN number:** UN 1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es):314.4. Packing group:IIHazard label:3Limited quantity Passenger:1 L

IATA-packing instructions - Passenger: 305
IATA-max. quantity - Passenger: 5 L
IATA-packing instructions - Cargo: 307
IATA-max. quantity - Cargo: 60 L

Other applicable information (air transport)

E2 : Y305 60 L

# **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)

H225 Highly flammable liquid and vapour. H226 Flammable liquid and vapour.

H315 Causes skin irritation.

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

H412 Harmful to aquatic life with long lasting effects.



according to Regulation (EC) No 1907/2006

# **One Coat 7 Universal**

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### **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.)