

according to Regulation (EC) No 1907/2006

Brilliant EverGlow

Revision date: 10.07.2017

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**

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: 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 (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.

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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 ³
Water solubility: (at 23 °C)	insoluble

Solubility in other solvents

Ethanol. (partially soluble)

9.2. Other information

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:** ---**Other applicable information**

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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**

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**

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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

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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:

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			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
64-17-5	ethanol, ethyl alcohol			35 - < 40 %
	200-578-6	603-002-00-5		
	Flam. Liq. 2; H225			
72869-86-4	Urethane dimethacrylate			20 - < 25 %
	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/m ³	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					
	Acute crustacea toxicity	EC50 9268 - 14221 mg/l	48 h	Daphnia magna	IUCLID	
72869-86-4	Urethane dimethacrylate					
	Acute fish toxicity	LC50 10.1 mg/l	96 h	Brachydanio rerio (zebra-fish)		OECD 203
868-77-9	2-hydroxyethyl methacrylate					
	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):	3
14.4. Packing group:	II
Hazard label:	3
Classification code:	F1
Limited quantity:	LQ4
Hazard 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): 3
14.4. Packing group: II
Hazard label: 3
Limited 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**

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

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Further Information

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