

according to Regulation (EC) No 1907/2006

Brilliant EverGlow Flow

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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

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

Harmful to aquatic life with long lasting effects.

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

TEGDMA

Ytterbium trifluoride

BISGMA

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

H315

Causes skin irritation.

H317

May cause an allergic skin reaction.

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H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 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 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.

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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			15 - < 20 %
	203-652-6			
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335			
13760-80-0	Ytterbium trifluoride			< 10 %
	237-354-2			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
1565-94-2	BISGMA			5 - < 10 %
	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.

Further Information

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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.

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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**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

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Changes in the physical state

Density (at 23 °C): 1.74 g/cm³
 Water solubility: insoluble
 (at 23 °C)

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.
 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
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

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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**

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**Changes**

* Data changed compared with the previous version

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

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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.)