

Revision date: 18.10.2017

Brilliant EverGlow Flow Print date: 20.02.2018

Page 1 of 6

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

1.1. Product identifier

Brilliant EverGlow Flow

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	+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: 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:

Pictograms:



Warning

Hazard statements

H315 H317 Causes skin irritation. May cause an allergic skin reaction.



Brilliant EverGlow Flow Revision date: 18.10.2017 Print date: 20.02.2018 Page 2 of 6 H319 Causes serious eye irritation. H335 May cause respiratory irritation. H412 Harmful to aquatic life with long lasting effects. **Precautionary statements** Wear protective gloves/protective clothing/eye protection/face protection. P280 P302+P352 IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. P333+P313 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.

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. 1, STOT SE 3; H315 H319 H317 H335				
13760-80-0	Ytterbium trifluoride	Ytterbium trifluoride			
	237-354-2				
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3				
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				
	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

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.



Brilliant EverGlow Flow

Revision date: 18.10.2017

Print date: 20.02.2018

Page 3 of 6

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

Safety Data Sheet



according to Regulation (EC) No 1907/2006

Brilliant EverGlow Flow			
Revision date: 18.10.2017	Print date: 20.02.2018	Page 4 of 6	
Changes in the physical state			
Density (at 23 °C):	1.74 g/cm³		
Water solubility: (at 23 °C)	insoluble		
Solubility in other solvents Ethanol. (partially soluble)			
0.2 Other information			

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	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 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



Brilliant EverGlow Flow

Revision date: 18.10.2017

Print date: 20.02.2018

Page 5 of 6

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

14.1. UN number:

Inland	waterway	/s transp	ort	(ADN))
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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)

- 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



Brilliant EverGlow Flow

Revision date: 18.10.2017

Print date: 20.02.2018

Page 6 of 6

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.)