

according to Regulation (EC) No 1907/2006

**Synergy D6 Flow**

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Print date: 20.11.2015

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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

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Directive 67/548/EEC or 1999/45/EC**

Indications of danger: Xi - Irritant  
R phrases:  
Irritating to eyes, respiratory system and skin.  
May cause sensitisation by skin contact.

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard categories:  
Skin corrosion/irritation: Skin Irrit. 2  
Serious eye damage/eye irritation: Eye Irrit. 2  
Respiratory/skin sensitization: Skin Sens. 1  
Specific target organ toxicity - single exposure: STOT SE 3  
Hazard Statements:  
Causes skin irritation.  
May cause an allergic skin reaction.  
Causes serious eye irritation.  
May cause respiratory irritation.

**2.2. Label elements****Hazardous components which must be listed on the label**

TEGDMA

Signal word: Warning

Pictograms: GHS07

**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.

**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.  
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
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.

**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**

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
216-367-7	BISGMA	10 - < 15 %
1565-94-2	Xi - Irritant R36/37/38	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335	
203-652-6	TEGDMA	5 - < 10 %
109-16-0	Xi - Irritant R36/37/38-43	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335	

Full text of R-, H- and EUH-phrases: 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**

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**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.

Restricted to professional users. 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):

1.8 g/cm<sup>3</sup>

Water solubility:

insoluble

(at 23 °C)

**Solubility in other solvents**

Ethanol. (partially soluble)

**SECTION 10: Stability and reactivity****10.2. Chemical stability**

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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 routes	Method	Dose	Species	Source
109-16-0	TEGDMA				
	oral	LD50	10837 mg/kg	Rat	literature value

**Irritation and corrosivity**

Causes skin irritation.  
Causes serious eye irritation.

**Sensitising effects**

May cause an allergic skin reaction. (TEGDMA)

**STOT-single exposure**

May cause respiratory irritation.

**SECTION 12: Ecological information****12.3. Bioaccumulative potential****Partition coefficient n-octanol/water**

CAS No	Chemical name	Log Pow
1565-94-2	BISGMA	4.94
109-16-0	TEGDMA	1.88

**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:** ---

**Inland waterways transport (ADN)**

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

**Marine transport (IMDG)**

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

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**Air transport (ICAO)****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****Relevant R-phrases (Number and full text)**

36/37/38 Irritating to eyes, respiratory system and skin.  
43 May cause sensitisation by skin contact.

**Relevant H- and EUH-phrases (Number and full text)**

H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

**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.)*