

according to Regulation (EC) No 1907/2006

Miris 2 Dentin-Enamel Shades

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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:

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

Hazard Statements:

Causes skin irritation.

May cause an allergic skin reaction.

Causes serious eye 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.
H319	Causes serious eye irritation.

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Precautionary statements

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- 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.
- P332+P313 If skin irritation 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**

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	
1565-94-2	Xi - Irritant R36/37/38	5 - < 10 %
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335	
276-957-5	UDMA	1 - < 5 %
72869-86-4	R52-53	
	Aquatic Chronic 3; H412	1 - < 5 %
203-652-6	TEGDMA	
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 (CO₂). Sand.

Additional information

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

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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.

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):

2.2 g/cm³Water solubility:
(at 23 °C)

insoluble

Solubility in other solvents

Ethanol. (partially soluble)

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SECTION 10: Stability and reactivity**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
72869-86-4	UDMA				
	oral	LD50	>2000 mg/kg	Rat	OECD 401
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)

SECTION 12: Ecological information**12.1. Toxicity**

CAS No	Chemical name					
	Aquatic toxicity	Method	Dose	[h] [d]	Species	Source
72869-86-4	UDMA					
	Acute fish toxicity	LC50	10.1 mg/l	96 h	Brachydanio rerio (zebra-fish)	OECD 203

12.2. Persistence and degradability

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
72869-86-4	UDMA			
	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
1565-94-2	BISGMA	4.94
72869-86-4	UDMA	3.39
109-16-0	TEGDMA	1.88

Further information

According to the criteria of the EC-classification and labelling "dangerous for the environment"

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(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:** ---**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. |
| 52 | Harmful to aquatic organisms. |
| 53 | May cause long-term adverse effects in the aquatic environment. |

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. |
| 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.)