

according to Regulation (EC) No 1907/2006

Miris 2 Dentin-Enamel Shades

Revision date: 19.08.2019

Print date: 19.08.2019

Page 1 of 5

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Miris 2 Dentin-Enamel Shades

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:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory or skin sensitisation: Skin Sens. 1

Hazard Statements:

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**

TEGDMA

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

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.

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.

according to Regulation (EC) No 1907/2006

Miris 2 Dentin-Enamel Shades

Revision date: 19.08.2019

Print date: 19.08.2019

Page 2 of 5

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

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
1565-94-2	BISGMA			5 - < 10 %
	216-367-7			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
72869-86-4	UDMA			1 - < 5 %
	276-957-5			
	Aquatic Chronic 3; H412			
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			

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.

according to Regulation (EC) No 1907/2006

Miris 2 Dentin-Enamel Shades

Revision date: 19.08.2019

Print date: 19.08.2019

Page 3 of 5

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**Changes in the physical state**

Density (at 23 °C): 2.0 g/cm³
Water solubility: insoluble
(at 23 °C)

Solubility in other solvents

Ethanol. (partially soluble)

9.2. Other information

*

SECTION 10: Stability and reactivity**10.4. Conditions to avoid**

Light.
UV-radiation/sunlight.

according to Regulation (EC) No 1907/2006

Miris 2 Dentin-Enamel Shades

Revision date: 19.08.2019

Print date: 19.08.2019

Page 4 of 5

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	
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	Dose	[h] [d]	Species	Source	Method
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" (93/21/EEC) the material/product is not to be classified as dangerous to the environment.

SECTION 13: Disposal considerations

according to Regulation (EC) No 1907/2006

Miris 2 Dentin-Enamel Shades

Revision date: 19.08.2019

Print date: 19.08.2019

Page 5 of 5

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**

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

Relevant H and EUH statements (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.)