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

1.1. Product identifier

DuoCem Base_Catalyst

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
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

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.
H335	May cause respiratory 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.

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	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
1565-94-2	BISGMA			10 - < 15 %
	216-367-7			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
109-16-0	TEGDMA			5 - < 10 %
	203-652-6			
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335			
	Zinc oxide coated			1 - < 5 %
	Skin Irrit. 3, Eye Irrit. 2B, Aquatic Acute 1 (M-Factor = 10), Aquatic Chronic 1; H316 H320 H400 H410			
94-36-0	dibenzoyl peroxide; benzoyl peroxide			< 1 %
	202-327-6	617-008-00-0		
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 H317			
7681-49-4	sodium fluoride			< 1 %
	231-667-8	009-004-00-7		
	Acute Tox. 3, Eye Irrit. 2, Skin Irrit. 2; H301 H319 H315 EUH032			

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 (CO_2). 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 - 8 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL
16984-48-8	Fluoride (inorganic as F)	-	2.5		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

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

Solubility in other solvents

Ethanol. (partially soluble)

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 route	Dose	Species	Source	Method
109-16-0	TEGDMA				
	oral	LD50 10837 mg/kg	Rat	literature value	
	Zinc oxide coated				
	oral	LD50 7950 mg/kg	Mouse.	literature value	
7681-49-4	sodium fluoride				
	oral	LD50 52 mg/kg	Rat	RTECS	

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

12.1. Toxicity

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] | [d]	Species	Source	Method
	Zinc oxide coated						
	Acute fish toxicity	LC50	1.1 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)	literature value	
	Acute crustacea toxicity	EC50 mg/l	0.098	48 h	Daphnia magna	literature value	
7681-49-4	sodium fluoride						
	Acute fish toxicity	LC50	925 mg/l	96 h	Gambusia affinis		
	Acute algae toxicity	ErC50	850 mg/l	72 h	Desmodesmus subspicatus		
	Acute crustacea toxicity	EC50	338 mg/l	48 h	Daphnia magna	IUCLID	

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: ---

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

EU regulatory information

Additional information

National regulatory information

SECTION 16: Other information

Relevant H and EUH statements (number and full text)

H241	Heating may cause a fire or explosion.
H301	Toxic if swallowed.
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.
EUH032	Contact with acids liberates very toxic gas.

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.)