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

1.1. Product identifier

Fill-Up!

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
Hazardous to the aquatic environment: Aquatic Chronic 3
Hazard Statements:
Causes skin irritation.
May cause an allergic skin reaction.
Causes serious eye irritation.
Harmful to aquatic life with long lasting effects.

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.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

P282	Wear suitable gloves and eye/face protection.

P262	Do not get in eyes, on skin, or on clothing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
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

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
3290-92-4	TMPTMA			10 - < 15 %
	221-950-4		01-2119542176-41	
	Aquatic Chronic 2; H411			
72869-86-4	UDMA			10 - < 15 %
	276-957-5			
	Aquatic Chronic 3; H412			
1565-94-2	BISGMA			5 - < 10 %
	216-367-7			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
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			
	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			

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.

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

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):	1.78 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
3290-92-4	TMPTMA					
	oral	LD50 mg/kg	> 5000	Rat	literature value	
	dermal	LD50 mg/kg	> 3000	Rabbit	literature value	
72869-86-4	UDMA					
	oral	LD50 mg/kg	>2000	Rat		OECD 401
109-16-0	TEGDMA					
	oral	LD50 mg/kg	10837	Rat	literature value	
	Zinc oxide coated					
	oral	LD50 mg/kg	7950	Mouse.	literature value	

Irritation and corrosivity

Causes skin irritation.
Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (TEGDMA) , (dibenzoyl peroxide; benzoyl peroxide)

SECTION 12: Ecological information

12.1. Toxicity

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] | [d]	Species	Source	Method
3290-92-4	TMPTMA						
	Acute fish toxicity	LC50	2 mg/l	96 h	Oncorhynchus mykiss	literature value	
	Acute algae toxicity	ErC50 mg/l	0.177	96 h	Pseudokirchneriella subcapitata	literature value	
	Acute crustacea toxicity	EC50 mg/l	> 9.22	48 h	Daphnia magna		
72869-86-4	UDMA						
	Acute fish toxicity	LC50 mg/l	10.1	96 h	Brachydanio rerio (zebra-fish)		OECD 203
	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	

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
3290-92-4	TMPTMA	3.53
72869-86-4	UDMA	3.39
1565-94-2	BISGMA	4.94
109-16-0	TEGDMA	1.88

12.5. Results of PBT and vPvB assessment

not applicable

Further information

--

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

National regulatory information

Additional information

SECTION 16: Other information

Relevant H and EUH statements (number and full text)

H241	Heating may cause a fire or explosion.
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.
H411	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 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.)