

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: Fill-Up!

Manufacturer: Coltene

SDS Expiry: 26 May 2025

Supplier Details: Henry Schein New Zealand
23 William Pickering Drive, Albany
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6 / 9

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2020
HSR002558

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared - March 2021

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

according to Regulation (EC) No 1907/2006

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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**Manufacturer**

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

Supplier

Company name: Henry Schein Halas
Australia
Street: 189 O'Riordan Street, Level 6,
Place: AU-NSW 2020 Mascot
Telephone: +61 1300 65 88 22

1.4. Emergency telephone number: 13 11 26 (Poisons Line – 24 hours)
Dial 000 (Fire/Ambulance/Police)

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.

Australia - This product is hazardous in accordance with WHS and non-dangerous as per ADG Code.

2.2. Label elements**Regulation (EC) No. 1272/2008**

Hazard components for labelling
TEGDMA

Signal word: Warning

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Pictograms:**Hazard statements**

Causes skin irritation.
 May cause an allergic skin reaction.
 Causes serious eye irritation.
 Harmful to aquatic life with long lasting effects.

Precautionary statements

Wear suitable gloves and eye/face protection.
 Do not get in eyes, on skin, or on clothing.
 If skin irritation or rash occurs: Get medical advice/attention.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
 Continue rinsing.
 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	
	GHS Classification			
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, 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.

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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**

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Occupational exposure limits

CAS No	Substance	ppm	mg/m ³	fib/cm ³	Category	Origin
128-37-0	2,6-Ditertiary-butyl-para-cresol	-	2		TWA (8 h)	
94-36-0	Benzoyl peroxid (Dibenzoyl peroxide)	-	5		TWA (8 h)	
1314-13-2	Zinc oxide, fume (Respirable Fraction)	-	2		TWA (8 h)	
		-	10		STEL (15 min)	

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: insoluble
 (at 23 °C)

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.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
3290-92-4	TMPTMA				
	oral	LD50 > 5000 mg/kg	Rat	literature value	
	dermal	LD50 > 3000 mg/kg	Rabbit	literature value	
72869-86-4	UDMA				
	oral	LD50 >2000 mg/kg	Rat		OECD 401
109-16-0	TEGDMA				
	oral	LD50 10837 mg/kg	Rat	literature value	
	Zinc oxide coated				
	oral	LD50 7950 mg/kg	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 0.177 mg/l	96 h	Pseudokirchneriella subcapitata	literature value	
	Acute crustacea toxicity	EC50 > 9.22 mg/l	48 h	Daphnia magna		
72869-86-4	UDMA					
	Acute fish toxicity	LC50 10.1 mg/l	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 0.098 mg/l	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.			

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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

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SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

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.

Australia - This material is not classified as Dangerous Goods as per ADG Code. HAZCHEM Code - none

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)**

Heating may cause a fire or explosion.

Causes skin irritation.

Causes mild skin irritation.

May cause an allergic skin reaction.

Causes serious eye irritation.

Causes eye irritation.

May cause respiratory irritation.

according to Regulation (EC) No 1907/2006

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Very toxic to aquatic life.
Very toxic to aquatic life with long lasting effects.
Toxic to aquatic life with long lasting effects.
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.)