

SAFETY DATA SHEETS

This SDS packet was issued with item:

077244833

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077180284 077180300

according to Regulation (EC) No 1907/2006

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Print date: 17.05.2016

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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

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:

Respiratory or skin sensitisation: Skin Sens. 1

Hazard Statements:

May cause an allergic skin reaction.

2.2. Label elements**Regulation (EC) No. 1272/2008****Hazard components for labelling**

maleic acid

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

H317 May cause an allergic skin reaction.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

according to Regulation (EC) No 1907/2006

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
110-16-7	maleic acid			1 - < 5 %
	203-742-5	607-095-00-3		
	Acute Tox. 4, Eye Irrit. 2, STOT SE 3, Skin Irrit. 2, Skin Sens. 1; H302 H319 H335 H315 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.

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**

Protect against: UV-radiation/sunlight.

Recommended storage temperature: 4 - 8°C

according to Regulation (EC) No 1907/2006

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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: liquid
 Colour: colourless

pH-Value: 2

Test method**Changes in the physical state**

Density (at 23 °C): 1.0 g/cm³
 Water solubility: easily soluble.
 (at 23 °C)

SECTION 10: Stability and reactivity**10.2. Chemical stability**

The product is chemically stable under recommended conditions of storage, use and temperature.

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
110-16-7	maleic acid			
	oral	ATE 500 mg/kg		
7681-49-4	sodium fluoride			
	oral	LD50 52 mg/kg	Rat	RTECS

Irritation and corrosivity

Based on available data, the classification criteria are not met.

according to Regulation (EC) No 1907/2006

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Sensitising effects

May cause an allergic skin reaction. (maleic acid)

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

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	
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

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)****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)**

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.

according to Regulation (EC) No 1907/2006

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H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
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.)

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

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

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**

2-hydroxyethyl methacrylate

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.

according to Regulation (EC) No 1907/2006

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P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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]			
868-77-9	2-hydroxyethyl methacrylate			45 - < 50 %
	212-782-2	607-124-00-X		
	Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1; H319 H315 H317			
1830-78-0	GDMA			25 - < 30 %
	217-388-4			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 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

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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****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: viscous, liquid
Colour: colourless

Test method**Changes in the physical state**

Density (at 23 °C): 1.1 g/cm³
Water solubility: insoluble
(at 23 °C)

Solubility in other solvents

Ethanol. (partially soluble)

SECTION 10: Stability and reactivity**10.2. Chemical stability**

The product is chemically stable under recommended conditions of storage, use and temperature.

10.4. Conditions to avoid

Light.
UV-radiation/sunlight.

according to Regulation (EC) No 1907/2006

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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
868-77-9	2-hydroxyethyl methacrylate			
	oral	LD50 5050 mg/kg	Rat	
1830-78-0	GDMA			
	oral	LD50 >2000 mg/kg	Rat	OECD 423

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (2-hydroxyethyl methacrylate)

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
868-77-9	2-hydroxyethyl methacrylate				
	Acute fish toxicity	LC50 227 mg/l	96 h	Pimephales promelas	
1830-78-0	GDMA				
	Acute fish toxicity	LC50 43.2 mg/l	96 h	Poecilia reticulata (Guppy)	

12.3. Bioaccumulative potential**Partition coefficient n-octanol/water**

CAS No	Chemical name	Log Pow
868-77-9	2-hydroxyethyl methacrylate	0,47

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:**

according to Regulation (EC) No 1907/2006

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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 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.

Further Information

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