

according to Regulation (EC) No 1907/2006

One Coat Self-Etching Bond 2

Revision date: 06.05.2015

Print date: 27.05.2015

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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

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Directive 67/548/EEC or 1999/45/EC**

Indications of danger: Xi - Irritant

R phrases:

Irritating to eyes, respiratory system and skin.

May cause sensitisation by skin contact.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory/skin sensitization: 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**Hazardous components which must be listed on the label**

2-hydroxyethyl methacrylate

Signal word: Warning

Pictograms: GHS07

**Hazard statements**

H315

Causes skin irritation.

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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.
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

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
212-782-2	2-hydroxyethyl methacrylate	35 - < 40 %
868-77-9	Xi - Irritant R36/38-43	
607-124-00-X	Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1; H319 H315 H317	
217-388-4	GDMA	20 - < 25 %
1830-78-0	Xi - Irritant R36/37/38	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335	
276-957-5	Urethane dimethacrylate	20 - < 25 %
72869-86-4	R52-53	
	Aquatic Chronic 3; H412	

Full text of R-, H- and EUH-phrases: 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

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Suitable extinguishing mediaWater. 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.

Restricted to professional users. 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): 1.13 g/cm³

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Water solubility:
(at 23 °C)

insoluble

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.

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 routes	Method	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
72869-86-4	Urethane dimethacrylate				
	oral	LD50	>2000 mg/kg	Rat	OECD 401

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	Method	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)	
72869-86-4	Urethane dimethacrylate					
	Acute fish toxicity	LC50	10.1 mg/l	96 h	Brachydanio rerio (zebra-fish)	OECD 203

12.2. Persistence and degradability

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CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
72869-86-4	Urethane dimethacrylate			
	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
868-77-9	2-hydroxyethyl methacrylate	0,47
72869-86-4	Urethane dimethacrylate	3.39

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 R-phrases (Number and full text)

36/37/38 Irritating to eyes, respiratory system and skin.
 36/38 Irritating to eyes and skin.
 43 May cause sensitisation by skin contact.

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- 52 Harmful to aquatic organisms.
53 May cause long-term adverse effects in the aquatic environment.

Relevant H- and EUH-phrases (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.)

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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

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Directive 67/548/EEC or 1999/45/EC**

Indications of danger: Xi - Irritant

R phrases:

Irritating to eyes, respiratory system and skin.

May cause sensitisation by skin contact.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory/skin sensitization: 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**Hazardous components which must be listed on the label**

2-hydroxyethyl methacrylate

Signal word: Warning

Pictograms: GHS07

**Hazard statements**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

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

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.
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

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
212-782-2	2-hydroxyethyl methacrylate	30 - < 35 %
868-77-9	Xi - Irritant R36/38-43	
607-124-00-X	Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1; H319 H315 H317	
217-388-4	GDMA	20 - < 25 %
1830-78-0	Xi - Irritant R36/37/38	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335	
239-268-0	Acrylamido sulphonic acid	5 - < 10 %
15214-89-8	C - Corrosive R34	
	Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H302 H315 H319 H335	

Full text of R-, H- and EUH-phrases: 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.

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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.

Restricted to professional users. 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: liquid
 Colour: colourless

Test method

Changes in the physical state

Density (at 23 °C): 1.11 g/cm³
 Water solubility:
 (at 23 °C) insoluble

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Solubility in other solvents

Ethanol.

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 routes	Method	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
15214-89-8	Acrylamido sulphonic acid		oral	LD50	1830 mg/kg	Rat	literature value

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	Method	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"

according to Regulation (EC) No 1907/2006

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(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****SECTION 16: Other information****Relevant R-phrases (Number and full text)**

34	Causes burns.
36/37/38	Irritating to eyes, respiratory system and skin.
36/38	Irritating to eyes and skin.
43	May cause sensitisation by skin contact.

Relevant H- and EUH-phrases (Number and full text)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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.)