

according to Regulation (EC) No 1907/2006

**One Coat Self-Etching Primer 1**

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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:

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.

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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			30 - < 35 %
	212-782-2	607-124-00-X		
	Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1; H319 H315 H317			
1830-78-0	GDMA			20 - < 25 %
	217-388-4			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
15214-89-8	Acrylamido sulphonic acid			5 - < 10 %
	239-268-0			
	Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H302 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 (CO<sub>2</sub>). 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**

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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****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/cm<sup>3</sup>Water solubility:  
(at 23 °C)

insoluble

**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.

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**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
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	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

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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 H and EUH statements (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.)*