

according to Regulation (EC) No 1907/2006

One Coat 7 Universal

Revision date: 05.05.2015

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:	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:

Flammable liquid: Flam. Liq. 3

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory or skin sensitisation: Skin Sens. 1

Hazard Statements:

Flammable liquid and vapour.

Causes skin irritation.

May cause an allergic skin reaction.

Causes serious eye irritation.

2.2. Label elements

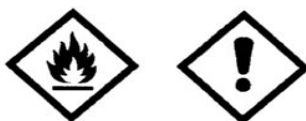
Regulation (EC) No. 1272/2008

Hazard components for labelling

2-hydroxyethyl methacrylate

Signal word: Warning

Pictograms:

**Hazard statements**

H226	Flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
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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.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P333+P313 If skin irritation or rash occurs: 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]			
64-17-5	ethanol, ethyl alcohol			35 - < 40 %
	200-578-6	603-002-00-5		
	Flam. Liq. 2; H225			
72869-86-4	Urethane dimethacrylate			20 - < 25 %
	276-957-5			
	Aquatic Chronic 3; H412			
868-77-9	2-hydroxyethyl methacrylate			5 - < 10 %
	212-782-2	607-124-00-X		
	Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1; H319 H315 H317			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Provide fresh air.

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 advice.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Water spray. Foam. Extinguishing powder. Carbon dioxide (CO₂). Sand.

Additional information

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

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6.1. Personal precautions, protective equipment and emergency procedures

Remove all sources of ignition. Provide adequate ventilation. Remove persons to safety.

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.

Advice on protection against fire and explosion

Keep away from sources of ignition. - No smoking.

Further information on handling

After use replace the closing cap immediately.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed and in a well-ventilated place.

Further information on storage conditions

Recommended storage temperature: 4 - 8 °C

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
64-17-5	Ethanol	1000	1920		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.

Respiratory protection

Provide adequate ventilation.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state: liquid
Colour: light yellow

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Odour:

characteristic

Test method**Changes in the physical state**

Flash point:

28 °C

Density:

1.0 g/cm³

Water solubility:

partially soluble

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

heat.

10.5. Incompatible materials

Oxidizing agents.

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
64-17-5	ethanol, ethyl alcohol	oral	LD50 6200 mg/kg	Rat	IUCLID
		inhalative (4 h) vapour	LC50 95,6 mg/l	Rat	RTECS
72869-86-4	Urethane dimethacrylate	oral	LD50 >2000 mg/kg	Rat	OECD 401
868-77-9	2-hydroxyethyl methacrylate	oral	LD50 5050 mg/kg	Rat	

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

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

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

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	
64-17-5	ethanol, ethyl alcohol					
	Acute crustacea toxicity	EC50 mg/l	9268 - 14221	48 h	Daphnia magna	IUCLID
72869-86-4	Urethane dimethacrylate					
	Acute fish toxicity	LC50	10.1 mg/l	96 h	Brachydanio rerio (zebra-fish)	OECD 203
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50	227 mg/l	96 h	Pimephales promelas	

12.2. Persistence and degradability

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
64-17-5	ethanol, ethyl alcohol	-0,31
72869-86-4	Urethane dimethacrylate	3,39
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:	UN 1170
14.2. UN proper shipping name:	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Classification code:	F1
Limited quantity:	LQ4
Hazard No:	33

Other applicable information (land transport)

Special provisions: 274
E3

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: 1
D/E
Special provisions: 274 601 640C
E2
: 2
Special provisions: 640C
Special provisions: 144 601

Marine transport (IMDG)

14.1. UN number: UN 1170
14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3
Limited quantity: 3 L
EmS: F-E, S-D

Other applicable information (marine transport)

Special provisions: 274, 330, 944
Special provisions: 944
Special provisions: 144, 330

Air transport (ICAO)

14.1. UN number: UN 1170
14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3
Limited quantity Passenger: 1 L
IATA-packing instructions - Passenger: 305
IATA-max. quantity - Passenger: 5 L
IATA-packing instructions - Cargo: 307
IATA-max. quantity - Cargo: 60 L

Other applicable information (air transport)

E2
: Y305
60 L

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)**

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
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.

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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: 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 Corr. 1B

Serious eye damage/eye irritation: Eye Dam. 1

Hazard Statements:

Causes severe skin burns and eye damage.

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

Phosphoric acid

Signal word:

Danger

Pictograms:**Hazard statements**

H314

Causes severe skin burns and eye damage.

Precautionary statements

P280

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

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.

P302+P352

IF ON SKIN: Wash with plenty of water.

P332+P313

If skin irritation occurs: 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

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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]			
7664-38-2	Phosphoric acid			35 - < 40 %
	231-633-2	015-011-00-6		
	Skin Corr. 1B; H314			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

Remove contaminated clothing immediately and dispose off safely.

After inhalation

Provide fresh air. In case of respiratory tract irritation, consult a physician.

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

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Medical treatment necessary.

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

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

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.

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for professional use only Keep out of the reach of children.
Observe instructions for use.

7.2. Conditions for safe storage, including any incompatibilities**Further information on storage conditions**

Recommended storage temperature: 4 - 23°C

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
7664-38-2	Orthophosphoric acid	-	1		TWA (8 h)	WEL
		-	2		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: Jelly
Colour: blue

pH-Value: < 1

Test method**Changes in the physical state**

Density (at 23 °C): 1.3 g/cm³

Water solubility: easily soluble.
(at 23 °C)

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

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Further information

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SECTION 11: Toxicological information

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11.1. Information on toxicological effects**Acute toxicity**

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

Irritation and corrosivity

Causes severe skin burns and eye damage.

Sensitising effects

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

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

CAS No	Chemical name				
	Aquatic toxicity	Dose	[h] [d]	Species	Source
7664-38-2	Phosphoric acid				
	Acute fish toxicity	LC50	138 mg/l	96 h	Gambusia affinis (Mosquito fish)

Further information

Do not allow uncontrolled leakage of product into 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:	UN 1805
14.2. UN proper shipping name:	PHOSPHORIC ACID SOLUTION
14.3. Transport hazard class(es):	8
14.4. Packing group:	III
Hazard label:	8
Classification code:	C1
Limited quantity:	5 L
Excepted quantity:	E1
Transport category:	3
Hazard No:	80
Tunnel restriction code:	E

Other applicable information (land transport): 3
E**Inland waterways transport (ADN)**

14.1. UN number:	—
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Marine transport (IMDG)

14.1. UN number:	UN 1805
14.2. UN proper shipping name:	PHOSPHORIC ACID SOLUTION
14.3. Transport hazard class(es):	8

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14.4. Packing group: III
Hazard label: 8
Special Provisions: 223
Limited quantity: 5 L
Excepted quantity: E1
EmS: F-A, S-B

Air transport (ICAO)

14.1. UN number: UN 1805
14.2. UN proper shipping name: PHOSPHORIC ACID SOLUTION
14.3. Transport hazard class(es): 8
14.4. Packing group: III
Hazard label: 8
Special Provisions: A3 A803
Limited quantity Passenger: 1 L
Passenger LQ: Y841
Excepted quantity: E1
IATA-packing instructions - Passenger: 852
IATA-max. quantity - Passenger: 5 L
IATA-packing instructions - Cargo: 856
IATA-max. quantity - Cargo: 60 L

Other applicable information (air transport)
60 L

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information****Additional information**

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

National regulatory information**SECTION 16: Other information****Relevant H and EUH statements (number and full text)**

H314 Causes severe skin burns and eye damage.

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.)