

according to Regulation (EC) No 1907/2006

**ParaBond Adhesive A**

Revision date: 06.05.2015

Print date: 07.05.2015

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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: F - Highly flammable, Xi - Irritant

R phrases:

Highly flammable.

Irritating to eyes, respiratory system and skin.

May cause sensitisation by skin contact.

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

Hazard categories:

Flammable liquid: Flam. Liq. 2

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:

Highly flammable liquid and vapour.

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

dibenzoyl peroxide; benzoyl peroxide

Signal word: Danger

Pictograms: GHS02-GHS07

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**Hazard statements**

H225	Highly flammable liquid and vapour.
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.
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	
200-578-6	ethanol, ethyl alcohol	25 - < 30 %
64-17-5	F - Highly flammable R11	
603-002-00-5	Flam. Liq. 2; H225	
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	
202-327-6	dibenzoyl peroxide; benzoyl peroxide	1 - < 5 %
94-36-0	E - Explosive, O - Oxidizing, Xi - Irritant R3-7-36-43	
617-008-00-0	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 H317	

Full text of R-, H- and EUH-phrases: see section 16.

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

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**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 (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**

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.

Restricted to professional users. 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**

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#### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL
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:	colourless
Odour:	characteristic

#### Test method

pH-Value:	6.5
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#### Changes in the physical state

Density:	1.02 g/cm <sup>3</sup>
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.

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CAS No	Chemical name				
	Exposure routes	Method	Dose	Species	Source
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50	5050 mg/kg	Rat	
64-17-5	ethanol, ethyl alcohol				
	oral	LD50	6200 mg/kg	Rat	IUCLID
	inhalative (4 h) vapour	LC50	95,6 mg/l	Rat	RTECS
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), (dibenzoyl peroxide; benzoyl peroxide)

#### 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	
64-17-5	ethanol, ethyl alcohol					
	Acute crustacea toxicity	EC50 mg/l	9268 - 14221	48 h	Daphnia magna	IUCLID
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
64-17-5	ethanol, ethyl alcohol	-0,31

#### 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.

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**SECTION 14: Transport information****Land transport (ADR/RID)**

<b>14.1. UN number:</b>	UN 1170
<b>14.2. UN proper shipping name:</b>	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
<b>14.3. Transport hazard class(es):</b>	3
<b>14.4. Packing group:</b>	II
Hazard label:	3
Classification code:	F1
Limited quantity:	LQ4
Hazard No:	33

**Other applicable information (land transport)**

Special provisions: 274  
E3  
: 1  
D/E  
Special provisions: 274 601 640C  
E2  
: 2  
Special provisions: 640C  
Special provisions: 144 601

**Marine transport (IMDG)**

<b>14.1. UN number:</b>	UN 1170
<b>14.2. UN proper shipping name:</b>	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
<b>14.3. Transport hazard class(es):</b>	3
<b>14.4. Packing group:</b>	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)**

<b>14.1. UN number:</b>	UN 1170
<b>14.2. UN proper shipping name:</b>	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
<b>14.3. Transport hazard class(es):</b>	3
<b>14.4. Packing group:</b>	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

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

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

- |          |  |
|----------|--|
| 03       | Extreme risk of explosion by shock, friction, fire or other sources of ignition. |
| 07       | May cause fire.  |
| 11       | Highly flammable.  |
| 36       | Irritating to eyes.  |
| 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)**

- |      |  |
|------|--|
| H225 | Highly flammable liquid and vapour.    |
| H241 | Heating may cause a fire or explosion. |
| 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.)*

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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: F - Highly flammable

R phrases:

Highly flammable.

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

Hazard categories:

Flammable liquid: Flam. Liq. 2

Hazard Statements:

Highly flammable liquid and vapour.

**2.2. Label elements**

Signal word: Danger

Pictograms: GHS02

**Hazard statements**

H225 Highly flammable liquid and vapour.

**Precautionary statements**

P233 Keep container tightly closed.

**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**



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**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		
200-578-6	ethanol, ethyl alcohol	85 - < 90 %
64-17-5	F - Highly flammable R11	
603-002-00-5	Flam. Liq. 2; H225	

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

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.

Restricted to professional users. 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.

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#### 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 <sup>3</sup>	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:	colourless
Odour:	characteristic

#### Test method

##### Changes in the physical state

Initial boiling point and boiling range:	78 - 80 °C
Flash point:	15 °C
Lower explosion limits:	3.5 vol. %
Upper explosion limits:	19 vol. %
Density:	0.84 g/cm <sup>3</sup>
Water solubility:	easily soluble.

### SECTION 10: Stability and reactivity

#### 10.4. Conditions to avoid

heat.

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### 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 routes	Method	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

#### Irritation and corrosivity

Hazards identification: Frequently or prolonged contact with skin may cause dermal irritation.

#### 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	Method	Dose	[h]   [d]	Species	Source
64-17-5	ethanol, ethyl alcohol					
	Acute crustacea toxicity	EC50 mg/l	9268 - 14221	48 h	Daphnia magna	IUCLID

### 12.3. Bioaccumulative potential

#### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
64-17-5	ethanol, ethyl alcohol	-0,31

#### 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)

<b>14.1. UN number:</b>	UN 1170
<b>14.2. UN proper shipping name:</b>	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
<b>14.3. Transport hazard class(es):</b>	3

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**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  
 : 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**

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

11 Highly flammable.

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

H225 Highly flammable liquid and vapour.

**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.)*