

according to Regulation (EC) No 1907/2006

ParaBond Adhesive A

Revision date: 06.05.2015

Print date: 22.02.2018

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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. 2

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:

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

2-hydroxyethyl methacrylate

dibenzoyl peroxide; benzoyl peroxide

Signal word: Danger**Pictograms:****Hazard statements**

H225	Highly flammable liquid and vapour.
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

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			
64-17-5	ethanol, ethyl alcohol			25 - < 30 %
	200-578-6	603-002-00-5		
	Flam. Liq. 2; H225			
1830-78-0	GDMA			20 - < 25 %
	217-388-4			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
94-36-0	dibenzoyl peroxide; benzoyl peroxide			1 - < 5 %
	202-327-6	617-008-00-0		
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 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.

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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

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
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.

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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

pH-Value:

6.5

Test method**Changes in the physical state**

Density:

1.02 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.

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CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
868-77-9	2-hydroxyethyl methacrylate					
	oral	LD50 mg/kg	5050	Rat		
64-17-5	ethanol, ethyl alcohol					
	oral	LD50 mg/kg	6200	Rat	IUCLID	
	inhalative (4 h) vapour	LC50	95,6 mg/l	Rat	RTECS	
1830-78-0	GDMA					
	oral	LD50 mg/kg	>2000	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	Dose	[h] [d]	Species	Source	Method
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	9268 - 14221 mg/l	48 h	Daphnia magna	IUCLID
1830-78-0	GDMA					
	Acute fish toxicity	LC50 mg/l	43.2	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

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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
: 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-TI/IATA-DGR)

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
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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**

SECTION 16: Other information**Relevant H and EUH statements (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:	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. 2

Hazard Statements:

Highly flammable liquid and vapour.

2.2. Label elements**Regulation (EC) No. 1272/2008****Signal word:** Danger**Pictograms:****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**3.2. Mixtures**

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

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

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

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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:	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 ³
Water solubility:	easily soluble.

SECTION 10: Stability and reactivity

10.4. Conditions to avoid

heat.

10.5. Incompatible materials

Oxidizing agents.

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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
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	Dose	[h] [d]	Species	Source	Method
64-17-5	ethanol, ethyl alcohol					
	Acute crustacea toxicity	EC50 9268 - 14221 mg/l	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)**

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

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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-TI/IATA-DGR)**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.

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Further Information

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(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)