

according to Regulation (EC) No 1907/2006

ParaBond Adhesive A

Revision date: 06.05.2015 Print date: 17.05.2016 Page 1 of 7

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

ParaBond Adhesive A

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 +41 (71) 75 75 300 Telephone: Telefax: +41 (71) 75 75 301 e-mail: info.ch@coltene.com www.coltene.com Internet: Responsible Department: Regulatory Affairs msds@coltene.com

1.4. Emergency telephone +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

number:

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. Labelelements

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.



according to Regulation (EC) No 1907/2006

ParaBond Adhesive A

Revision date: 06.05.2015 Print date: 17.05.2016 Page 2 of 7

H319 Causes serious eyeirritation. 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					
	EC No	Index No	REACH No			
	Classification according	g to Regulation (EC) No. 1272/2008 [CLP]			
868-77-9	2-hydroxyethyl methaci	ylate		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					
	217-388-4					
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335					
94-36-0	dibenzoyl peroxide; benzoyl peroxide					
	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.

SECTION 5: Firefighting measures



according to Regulation (EC) No 1907/2006

ParaBond Adhesive A

Revision date: 06.05.2015 Print date: 17.05.2016 Page 3 of 7

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. Controlparameters

Exposure limits(EH40)

CAS No	Substance	ppm	mg/m³	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.



according to Regulation (EC) No 1907/2006

ParaBond Adhesive A

Revision date: 06.05.2015 Print date: 17.05.2016 Page 4 of 7

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

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.

CAS No	Chemical name							
	Exposure route	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)



according to Regulation (EC) No 1907/2006

ParaBond Adhesive A

Revision date: 06.05.2015 Print date: 17.05.2016 Page 5 of 7

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	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.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1.</u> <u>UN number:</u> UN 1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es):314.4. Packing group:IIHazard label:3Classification code:F1Limited quantity:LQ4Hazard No:33

Other applicable information (land transport)

Special provisions: 274

E3 : 1 D/E

Special provisions: 274 601 640C

Ë2

: 2



according to Regulation (EC) No 1907/2006

ParaBond Adhesive A

Revision date: 06.05.2015 Print date: 17.05.2016 Page 6 of 7

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)

<u>14.1. UN number:</u> UN 1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es):314.4. Packing group:IIHazard label:3Limited 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. 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.

Coltène/WhaledentAG

Safety Data Sheet



according to Regulation (EC) No 1907/2006

ParaBond Adhesive A

Revision date: 06.05.2015 Print date: 17.05.2016 Page 7 of 7

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



according to Regulation (EC) No 1907/2006

ParaBond Adhesive B

Revision date: 20.04.2015 Print date: 17.05.2016 Page 1 of 6

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

ParaBond Adhesive B

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

Coltène/Whaledent AG Company name: 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 +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

number:

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



Revision date: 20.04.2015

according to Regulation (EC) No 1907/2006

ParaBond Adhesive B

Revision date: 20.04.2015 Print date: 17.05.2016 Page 2 of 6

Hazardous components

CAS No	Chemical name	chemical name					
	EC No	EC No Index No REACH No					
	Classification according	Classification according to Regulation (EC) No. 1272/2008 [CLP]					
64-17-5	ethanol, ethyl alcohol	ethanol, ethyl alcohol					
	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



according to Regulation (EC) No 1907/2006

ParaBond Adhesive B

Revision date: 20.04.2015 Print date: 17.05.2016 Page 3 of 6

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/m³	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/cm³

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



according to Regulation (EC) No 1907/2006

ParaBond Adhesive B

Revision date: 20.04.2015 Print date: 17.05.2016 Page 4 of 6

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	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		
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)

14.1. UN number: UN 1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es):314.4. Packing group:IIHazard label:3Classification code:F1Limited quantity:LQ4Hazard No:33



according to Regulation (EC) No 1907/2006

ParaBond Adhesive B

Revision date: 20.04.2015 Print date: 17.05.2016 Page 5 of 6

Other applicable information (land transport)

Special provisions: 274

E3 : 1 D/E

Special provisions: 274 601 640C

E2

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):314.4. Packing group:IIHazard label:3Limited 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.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our

Coltène/Whaledent AG

Safety Data Sheet



according to Regulation (EC) No 1907/2006

ParaBond Adhesive B

Revision date: 20.04.2015 Print date: 17.05.2016 Page 6 of 6

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.)



according to Regulation (EC) No 1907/2006

ParaBond Non-Rinse Conditioner

Revision date: 06.05.2015 Print date: 17.05.2016 Page 1 of 5

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

ParaBond Non-Rinse Conditioner

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 +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

number:

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

Hazard Statements: 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

Jigilai word.

Pictograms:



Hazard statements

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.

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if



according to Regulation (EC) No 1907/2006

ParaBond Non-Rinse Conditioner

Revision date: 06.05.2015 Print date: 17.05.2016 Page 2 of 5

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	on (EC) No. 1272/2008 [CLP]	•		
868-77-9	2-hydroxyethyl methacrylate				
	212-782-2	607-124-00-X			
	Eye Irrit. 2, Skin Irrit. 2, Skin Sens.	1; H319 H315 H317			
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 (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



according to Regulation (EC) No 1907/2006

ParaBond Non-Rinse Conditioner

Revision date: 06.05.2015 Print date: 17.05.2016 Page 3 of 5

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: 1.2 g/cm³

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.



according to Regulation (EC) No 1907/2006

		ParaBond Nor	n-Rinse Conditioner		
Revision da	ate: 06.05.2015	Print da	ate: 17.05.2016		Page 4 of 5
CAS No	Chemical name				
	Exposure route	Dose	Species	Source	
868-77-9	2-hydroxyethyl methacryla	ite			

CAS No	Chemical name				
	Exposure route	Dose		Species	Source
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50	5050 mg/kg	Rat	
15214-89-8	Acrylamido sulphonic acid				
	oral	LD50	1830 mg/kg	Rat	literature value

Irritation and corrosivity

Causes skin irritation.

Causes serious eve irritation.

Sensitising effects

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

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	

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 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.



according to Regulation (EC) No 1907/2006

ParaBond Non-Rinse Conditioner

Revision date: 06.05.2015 Print date: 17.05.2016 Page 5 of 5

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)

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.)



according to Regulation (EC) No 1907/2006

ParaCore

Print date: 17.05.2016 Revision date: 05.05.2015 Page 1 of 6

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

ParaCore

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 +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

number:

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

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements: Causes skin irritation.

May cause an allergic skin reaction.

Causes serious eve irritation.

Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

TEGDMA

Signal word: Warning

Pictograms:



Hazard statements

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.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.



according to Regulation (EC) No 1907/2006

ParaCore

Revision date: 05.05.2015 Print date: 17.05.2016 Page 2 of 6

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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 Regulati	on (EC) No. 1272/2008 [CLP]	•		
72869-86-4	UDMA			10 - < 15 %	
	276-957-5				
	Aquatic Chronic 3; H412	•			
3290-92-4	ТМРТМА			10 - < 15 %	
	221-950-4		01-2119542176-41		
	Aquatic Chronic 2; H411	•			
1565-94-2	BISGMA			5 - < 10 %	
	216-367-7				
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3	; H315 H319 H335			
109-16-0	TEGDMA	1 - < 5 %			
	203-652-6				
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens.	1, STOT SE 3; H315 H319 H317	H335		
94-36-0	dibenzoyl peroxide; benzoyl peroxid	de		< 1 %	
	202-327-6	617-008-00-0			
	Org. Perox. B, Eye Irrit. 2, Skin Ser	ns. 1; H241 H319 H317			
7681-49-4	sodium fluoride			< 1 %	
	231-667-8	009-004-00-7			
	Acute Tox. 3, Eye Irrit. 2, Skin Irrit. 2; H301 H319 H315 EUH032				

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



according to Regulation (EC) No 1907/2006

ParaCore

Revision date: 05.05.2015 Print date: 17.05.2016 Page 3 of 6

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

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.

$\underline{\textbf{7.2. Conditions for safe storage, including any incompatibilities}}$

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

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		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.



according to Regulation (EC) No 1907/2006

ParaCore

Revision date: 05.05.2015 Print date: 17.05.2016 Page 4 of 6

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Paste Colour: off-white

Test method

Changes in the physical state

Density (at 23 °C):

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 route	Dose		Species	Source
72869-86-4	UDMA				
	oral	LD50	>2000 mg/kg	Rat	OECD 401
3290-92-4	ТМРТМА				
	oral	LD50	> 5000 mg/kg	Rat	literature value
	dermal	LD50	> 3000 mg/kg	Rabbit	literature value
109-16-0	TEGDMA				
	oral	LD50	10837 mg/kg	Rat	literature value
7681-49-4	sodium fluoride				
	oral	LD50	52 mg/kg	Rat	RTECS

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (TEGDMA), (dibenzoyl peroxide; benzoyl peroxide)

SECTION 12: Ecological information

12.1. Toxicity



according to Regulation (EC) No 1907/2006

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Revision date: 05.05.2015 Print date: 17.05.2016 Page 5 of 6

CAS No	Chemical name	Chemical name					
	Aquatic toxicity	Dose		[h] [d]	Species	Source	
72869-86-4	UDMA						
	Acute fish toxicity	LC50	10.1 mg/l	96 h	Brachydanio rerio (zebra-fish)	OECD 203	
3290-92-4	ТМРТМА						
	Acute fish toxicity	LC50	2 mg/l	96 h	Oncorhynchus mykiss	literature value	
	Acute algae toxicity	ErC50	0.177 mg/l	96 h	Pseudokirchneriella subcapitata	literature value	
	Acute crustacea toxicity	EC50	> 9.22 mg/l	48 h	Daphnia magna		
7681-49-4	sodium fluoride						
	Acute fish toxicity	LC50	925 mg/l	96 h	Gambusia affinis		
	Acute algae toxicity	ErC50	850 mg/l	72 h	Desmodesmus subspicatus		
	Acute crustacea toxicity	EC50	338 mg/l	48 h	Daphnia magna	IUCLID	

12.2. Persistence and degradability

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
72869-86-4	UDMA			
	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
72869-86-4	UDMA	3.39
3290-92-4	TMPTMA	3.53
1565-94-2	BISGMA	4.94
109-16-0	TEGDMA	1.88

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)

<u>14.1. UN number:</u> ---

Inland waterways transport (ADN)

<u>14.1. UN number:</u> ---

Marine transport (IMDG)

<u>14.1. UN number:</u> ---



according to Regulation (EC) No 1907/2006

ParaCore

Revision date: 05.05.2015 Print date: 17.05.2016 Page 6 of 6

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 H and EUH statements (number and full text)

Π 24 Ι	nealing may cause a life of explosion.
H301	Toxic if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H411	Toxic to aquatic life with long lasting effects.

H411 IOXIC to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.
EUH032 Contact with acids liberates very toxic gas.

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.)