

according to Regulation (EC) No 1907/2006

ParaCore

Revision date: 05.05.2015

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**

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: 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 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 eye 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.

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P302+P352 IF ON SKIN: Wash with plenty of water.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 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] | | | |
| 72869-86-4 | UDMA | | | 10 - < 15 % |
| | 276-957-5 | | | |
| | Aquatic Chronic 3; H412 | | | |
| 3290-92-4 | TMPTMA | | | 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 peroxide | | | < 1 % |
| | 202-327-6 | 617-008-00-0 | | |
| | Org. Perox. B, Eye Irrit. 2, Skin Sens. 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

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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.

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/m ³ | 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.

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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): 2.1 g/cm³
 Water solubility: insoluble
 (at 23 °C)

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 | Method |
| 72869-86-4 | UDMA | | | | |
| | oral | LD50 >2000 mg/kg | Rat | | OECD 401 |
| 3290-92-4 | TMPTMA | | | | |
| | 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

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12.1. Toxicity

| CAS No | Chemical name | | | | | |
|------------|--------------------------|---------------|-----------|---------|------------------------------------|------------------|
| | Aquatic toxicity | Dose | [h] [d] | Species | Source | Method |
| 72869-86-4 | UDMA | | | | | |
| | Acute fish toxicity | LC50 mg/l | 10.1 | 96 h | Brachydanio rerio (zebra-fish) | OECD 203 |
| 3290-92-4 | TMPTMA | | | | | |
| | Acute fish toxicity | LC50 | 2 mg/l | 96 h | Oncorhynchus mykiss | literature value |
| | Acute algae toxicity | ErC50 mg/l | 0.177 | 96 h | Pseudokirchneriella subcapitata | literature value |
| | Acute crustacea toxicity | EC50 mg/l | > 9.22 | 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)

14.1. UN number: ---

Inland waterways transport (ADN)

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14.1. UN number: ---**Marine transport (IMDG)****14.1. UN number:** ---**Air transport (ICAO-TI/IATA-DGR)****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)**

| | |
|--------|--|
| H241 | Heating may cause a fire or 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. |
| 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.)

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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: | 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
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**

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**

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

| | |
|-------------------------|--|
| 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

according to Regulation (EC) No 1907/2006

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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.

according to Regulation (EC) No 1907/2006

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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 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**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

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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 | | | 45 - < 50 % |
| | 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

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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.

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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 | | |
| 15214-89-8 | Acrylamido sulphonic acid | | | | | |
| | oral | LD50 mg/kg | 1830 | Rat | literature value | |

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

| 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 | |

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-TI/IATA-DGR)****14.1. UN number:** ---**Other applicable information**

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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)**

| | |
|------|--------------------------------------|
| 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.)