SAFETY DATA SHEETS

This SDS packet was issued with item:

077244833

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077180284 077180300



according to Regulation (EC) No 1907/2006

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

1.1. Product identifier

A.R.T. Bond Primer 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

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:

Respiratory or skin sensitisation: Skin Sens. 1

Hazard Statements:

May cause an allergic skin reaction.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

maleic acid

Signal word: Warning

Pictograms:



Hazard statements

H317 May cause an allergic skin reaction.

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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures



according to Regulation (EC) No 1907/2006

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Hazardous components

| CAS No | Chemical name | | | | | | |
|-----------|--|--------------|----------|-------|--|--|--|
| | EC No | Index No | REACH No | | | | |
| | Classification according to Regulation (EC) No. 1272/2008 [CLP] | | | | | | |
| 110-16-7 | maleic acid | | | | | | |
| | 203-742-5 | 607-095-00-3 | | | | | |
| | Acute Tox. 4, Eye Irrit. 2, STOT SE 3, Skin Irrit. 2, Skin Sens. 1; H302 H319 H335 H315 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.

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

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

Protect against: UV-radiation/sunlight.

Recommended storage temperature: 4 - 8°C



according to Regulation (EC) No 1907/2006

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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

pH-Value: 2

Changes in the physical state

Density (at 23 °C): 1.0 g/cm³
Water solubility: easily soluble. (at 23 °C)

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 | | | |
| 110-16-7 | maleic acid | maleic acid | | | | | | |
| | oral | ATE | 500 mg/kg | | | | | |
| 7681-49-4 | sodium fluoride | | | | | | | |
| | oral | LD50 | 52 mg/kg | Rat | RTECS | | | |

Irritation and corrosivity

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



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Sensitising effects

May cause an allergic skin reaction. (maleic acid)

SECTION 12: Ecological information

12.1. Toxicity

| CAS No | Chemical name | | | | | | | | |
|-----------|--------------------------|-------|----------|-----------|-------------------------|--------|--|--|--|
| | Aquatic toxicity | Dose | | [h] [d] | Species | Source | | | |
| 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 | | | |

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> ---

Air transport (ICAO)

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

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)

H301 Toxic if swallowed. H302 Harmful if swallowed. H315 Causes skin irritation.

H317 May cause an allergic skin reaction.



according to Regulation (EC) No 1907/2006

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H319 Causes serious eye irritation. H335 May cause respiratory irritation.

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

A.R.T. Bond Primer 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: 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

Specific target organ toxicity - single exposure: STOT SE 3

Hazard Statements: 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

Signal word: Warning

Pictograms:



Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.

Precautionary statements

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



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|---------------------------|--|-------------|
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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. | |
| 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 advise on la | halling | |

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 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 | | | | | |
| 1830-78-0 | O GDMA | | | | | |
| | 217-388-4 | | | | | |
| | Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; 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.



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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

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: viscous, liquid colour: colourless

Test method

Changes in the physical state

Density (at 23 °C):

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.



according to Regulation (EC) No 1907/2006

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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 | 2-hydroxyethyl methacrylate | | | | | | |
| | oral | LD50 | 5050 mg/kg | Rat | | | | |
| 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)

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 | | | |
| 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 |

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> ---



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Inland waterways transport (ADN)

14.1. UN number: ---

Marine transport (IMDG)

14.1. UN number: ---

Air transport (ICAO)

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

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)

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.)