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

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

Safety Data Sheet

Coltene/Whaledent AG

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ParaCore

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

<table>
<thead>
<tr>
<th>CAS No</th>
<th>Chemical name</th>
<th>Quantity</th>
<th>EC No</th>
<th>Index No</th>
<th>REACH No</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
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<td></td>
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</tbody>
</table>

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

<table>
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<th>Chemical name</th>
<th>Index No</th>
<th>REACH No</th>
<th>Classification</th>
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</thead>
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<tr>
<td>72869-86-4</td>
<td>UDMA</td>
<td></td>
<td></td>
<td>Aquatic Chronic 3; H412</td>
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<tr>
<td>276-957-5</td>
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<tr>
<td>3290-92-4</td>
<td>TMPTMA</td>
<td></td>
<td></td>
<td>Aquatic Chronic 2; H411</td>
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<tr>
<td>221-950-4</td>
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<td></td>
</tr>
<tr>
<td>1565-94-2</td>
<td>BISGMA</td>
<td></td>
<td></td>
<td>Skin Irr. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335</td>
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<tr>
<td>216-367-7</td>
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<td></td>
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<tr>
<td>109-16-0</td>
<td>TEGDMA</td>
<td></td>
<td></td>
<td>Skin Irr. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H317 H335</td>
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<tr>
<td>203-652-6</td>
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<td>94-36-0</td>
<td>dibenzoyl peroxide; benzoyl peroxide</td>
<td></td>
<td></td>
<td>Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 H317</td>
</tr>
<tr>
<td>202-327-6</td>
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<td></td>
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<tr>
<td>7681-49-4</td>
<td>sodium fluoride</td>
<td></td>
<td></td>
<td>Acute Tox. 3, Eye Irrit. 2, Skin Irrit. 2; H301 H319 H315 EUH032</td>
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<tr>
<td>231-667-8</td>
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</tbody>
</table>

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

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)

<table>
<thead>
<tr>
<th>CAS No</th>
<th>Substance</th>
<th>ppm</th>
<th>mg/m³</th>
<th>fibres/ml</th>
<th>Category</th>
<th>Origin</th>
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</thead>
<tbody>
<tr>
<td>94-36-0</td>
<td>Dibenzoyl peroxide</td>
<td>-</td>
<td>5</td>
<td>-</td>
<td>TWA (8 h)</td>
<td>WEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-</td>
<td></td>
<td></td>
<td>STEL (15 min)</td>
<td>WEL</td>
</tr>
</tbody>
</table>

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: Paste
Colour: off-white

Test method

Changes in the physical state

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

<table>
<thead>
<tr>
<th>CAS No</th>
<th>Chemical name</th>
<th>Exposure route</th>
<th>Dose</th>
<th>Species</th>
<th>Source</th>
<th>Method</th>
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</thead>
<tbody>
<tr>
<td>72869-86-4</td>
<td>UDMA</td>
<td>oral</td>
<td>LD50 mg/kg</td>
<td>&gt;2000</td>
<td>Rat</td>
<td>OECD 401</td>
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<tr>
<td>3290-92-4</td>
<td>TMPTMA</td>
<td>oral</td>
<td>LD50 mg/kg</td>
<td>&gt; 5000</td>
<td>Rat</td>
<td>literature value</td>
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<tr>
<td></td>
<td></td>
<td>dermal</td>
<td>LD50 mg/kg</td>
<td>&gt; 3000</td>
<td>Rabbit</td>
<td>literature value</td>
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<tr>
<td>109-16-0</td>
<td>TEGDMA</td>
<td>oral</td>
<td>LD50 mg/kg</td>
<td>10837</td>
<td>Rat</td>
<td>literature value</td>
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<tr>
<td>7681-49-4</td>
<td>sodium fluoride</td>
<td>oral</td>
<td>LD50 mg/kg</td>
<td>52</td>
<td>Rat</td>
<td>RTECS</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>CAS No</th>
<th>Chemical name</th>
<th>Aquatic toxicity</th>
<th>Dose</th>
<th>[h]</th>
<th>[d]</th>
<th>Species</th>
<th>Source</th>
<th>Method</th>
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<tbody>
<tr>
<td>72869-86-4</td>
<td>UDMA</td>
<td>Acute fish toxicity</td>
<td>LC50</td>
<td>10.1</td>
<td>96 h</td>
<td>Brachydanio rerio (zebra-fish)</td>
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<tr>
<td>3290-92-4</td>
<td>TMPTMA</td>
<td>Acute fish toxicity</td>
<td>LC50</td>
<td>2 mg/l</td>
<td>96 h</td>
<td>Oncorhynchus mykiss literature value</td>
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<tr>
<td></td>
<td></td>
<td>Acute algae toxicity</td>
<td>ErC50</td>
<td>0.177</td>
<td>96 h</td>
<td>Pseudokirchneriella subcapitata</td>
<td>literature value</td>
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<tr>
<td></td>
<td></td>
<td>Acute crustacea toxicity</td>
<td>EC50</td>
<td>&gt; 9.22</td>
<td>48 h</td>
<td>Daphnia magna</td>
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<td>7681-49-4</td>
<td>sodium fluoride</td>
<td>Acute fish toxicity</td>
<td>LC50</td>
<td>925 mg/l</td>
<td>96 h</td>
<td>Gambusia affinis</td>
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<td>Acute algae toxicity</td>
<td>ErC50</td>
<td>850 mg/l</td>
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<td>Desmodesmus subspicatus</td>
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<td></td>
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<td>Acute crustacea toxicity</td>
<td>EC50</td>
<td>338 mg/l</td>
<td>48 h</td>
<td>Daphnia magna</td>
<td>IUCLID</td>
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</table>

### 12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>CAS No</th>
<th>Chemical name</th>
<th>Method</th>
<th>Value</th>
<th>d</th>
<th>Source</th>
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<td>72869-86-4</td>
<td>UDMA</td>
<td>OECD 301 F</td>
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<td>28</td>
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</tbody>
</table>

Product is not easily biodegradable.

### 12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDMA</td>
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<td>TMPTMA</td>
<td>3.53</td>
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<td>BISGMA</td>
<td>4.94</td>
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<tr>
<td>TEGDMA</td>
<td>1.88</td>
</tr>
</tbody>
</table>

### 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

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.)