

SAFETY DATA SHEETS

This SDS packet was issued with item:

077213135

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).

077213002 077213028 077213036 077213044 077213119 077213127

Material Safety Data Sheet

May be used to comply with OSHA's Hazard Communication Standard.

Identity **Cool Temp**

Section I

Manufacturer's Name **Coltène/Whaledent Inc.**

Emergency Tel. No. **201-512-8000**

Address **750 Corporate Drive
Mahwah, NJ 07430**

Tel. No. for Information **201-512-8000**

Date Prepared **2001-02**

Signature of Preparer _____

Section II - Hazardous Ingredients / Identity Information

| Hazardous Components (Specific Chemical Identity; Common Name(s)) | OSHA PEL | ACGIH TLV | Other Limits Recommended (optional) | % |
|--|----------|-----------|--|---|
| Methacrylates | | | | |

Section III - Physical/Chemical Characteristics

| | | | |
|-------------------------|---------------------|------------------|----------------------------|
| Boiling Point | > 150 °C | Specific Gravity | 1.6 |
| Vapor Pressure at °C | n.a. (mm Hg) | Melting Point | n.k. °C |
| Vapor Density (AIR = 1) | > 1 | Evaporation Rate | >> 100 (Butyl acetate = 1) |
| Solubility in Water | none | | |
| Appearance and Odor | tooth colored paste | | |

Section IV - Fire and Explosion Hazard Data

| | | | | |
|------------------------------------|--|------------------------|------------|------------|
| Flash Point | > 100 °C | Flammable Limits at °C | LEL n.a. % | UEL n.a. % |
| Extinguishing Media | water fog, spray, foam, halones, CO ₂ , dry extinguishing media, sand | | | |
| Special Fire Fighting Procedures | none | | | |
| Unusual Fire and Explosion Hazards | none | | | |

Section V - Reactivity Data

| | | |
|---------------------------------------|--|-----------------------------------|
| Stability | Unstable <input type="checkbox"/> | Conditions to Avoid |
| | Stable <input checked="" type="checkbox"/> | strong oxides, temperature > 25°C |
| Incompatibility (Materials to Avoid) | | none |
| Hazardous Decomposition or Byproducts | | none |
| Hazardous Polymerization | May Occur <input type="checkbox"/> | Conditions to Avoid |
| | Will Not Occur <input checked="" type="checkbox"/> | none |

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Section VI - Health Hazard Data

| | | | |
|------------------------------------|---|-------------------------------------|--------------------------|
| Routes of Entry | Inhalation | Skin | Ingestion |
| | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Health Hazards (Acute and Chronic) | Unpolymerized resin may cause an allergic reaction. | | |
| Carcinogenicity | NTP | IARC Monographs | OSHA Regulated |
| | none | | |
| Signs and Symptoms of Exposure | Contact allergy. | | |
| Medical Conditions | n.n. | | |
| Generally Aggravated by Exposure | | | |
| Emergency and First Aid Procedures | Wash with soap. | | |

Section VII - Precautions for Safe Handling and Use

| | |
|---|---|
| Steps to Be Taken | Remove cured composite. |
| In Case Material is Released or Spilled | Polymerized dental composite materials do not cause disturbances in sewage plants. |
| Waste Disposal Method | Garbage disposal |
| Precautions to Be Taken in Handling and Storing | Store in a cold place. Avoid direct contact with skin or mucous membrane. |
| Other Precautions | Handle composite with spatula or syringe. Wear gloves. The product should only be supplied to dentists or dental technicians or upon their instructions. |

Section VIII - Control Measures

| | |
|--|---|
| Respiratory Protection (Specify Type) | not required |
| Ventilation | |
| Local Exhaust | - |
| Mechanical (General) | - |
| Special | - |
| Other | - |
| Protective Gloves <u>X</u> | Eye Protection - |
| Other Protective Clothing or Equipment | - |
| Work / Hygienic Practices | Wash hands before breaks and after the end of a day's work. |

Section IX - Information

New MSDS

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1. Identification of the substance/preparation and of the company/undertaking**Identification of the substance or preparation**

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Use of the substance/preparation

for dental use only

Company/undertaking identification

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@coltenewhaledent.ch
Internet : www.coltenewhaledent.com

2. Hazards identification**Classification**

Indications of danger : Irritant

R-phrases :

Irritating to eyes and skin.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

3. Composition/information on ingredients**Chemical characterization (Mixture)****Hazardous components**

| EC-No. | CAS-No. | Chemical name | Quantity | Classification |
|-----------|-----------|-------------------|-----------|-----------------|
| | | UDMA | 30 - 35 % | Xi R36/38 |
| 205-016-3 | 131-17-9 | diallyl phthalate | 10 - 15 % | Xn, N R22-50-53 |
| 221-950-4 | 3290-92-4 | TMPTMA | 1 - 5 % | N R51-53 |

Full text of each relevant R phrase can be found in heading 16.

4. 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.

5. Fire-fighting measures**Suitable extinguishing media**

Water. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.

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Additional information

Extinguishing materials should be selected according to the surrounding area.

6. Accidental release measures**Personal precautions**

Avoid contact with skin and eyes.

Environmental precautions

Do not empty into drains or the aquatic environment.

Methods for cleaning up/taking up

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated area thoroughly.

7. Handling and storage**Handling****Advice on safe handling**

Avoid contact with skin and eyes.

Restricted to professional users. Keep out of the reach of children.

Further information on handling

After use replace the closing cap immediately.

Storage**Further information on storage conditions**

Substances sensitive to light.

Recommended storage temperature: 4 - 23 °C

8. Exposure controls/personal protection**Exposure limit values****Exposure limits (EH40)**

| CAS-No. | Chemical name | ml/m ³ | mg/m ³ | F/ml | Category | Origin |
|----------|-------------------|-------------------|-------------------|------|---------------|--------|
| 131-17-9 | Diallyl phthalate | - | 5 | | TWA (8 h) | WEL |
| | | - | - | | STEL (15 min) | WEL |

Exposure controls**Protective and hygiene measures**

When using do not eat, drink or smoke.

Hand protection

Single-use gloves. Suitable material: PVC (Polyvinyl chloride).

Roeko Glovyl - or comparable makes from other companies.

Eye protection

Framed glasses.

Skin protection

Lab apron.

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9. Physical and chemical properties**General information**

Physical state : Paste
Colour : off-white

Important health, safety and environmental information

Test method

Changes in the physical state

Density (at 23 °C) : 2.2 g/cm³
Water solubility (at 23 °C) : insoluble
Solubility in other solvents : Ethanol. (partially soluble)

10. Stability and reactivity**Conditions to avoid**

Light.
UV-radiation/sunlight.

11. Toxicological information**12. Ecological information****13. Disposal considerations****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.

14. Transport information**Land transport (ADR/RID)**

UN number : ---
Warning plate

Inland waterways transport

UN number : ---

Marine transport

UN number : ---

Air transport

UN/ID number : ---

Further Information

Not a hazardous material with respect to these transportation regulations.

15. Regulatory information**Labelling**

Danger symbols : Xi - Irritant

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R phrases

- 36/38 Irritating to eyes and skin.
52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S phrases

- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
37 Wear suitable gloves.

National regulatory information**16. Other information****Full text of R-phrases referred to under sections 2 and 3**

- 22 Harmful if swallowed.
36/38 Irritating to eyes and skin.
50 Very toxic to aquatic organisms.
51 Toxic to aquatic organisms.
52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
53 May cause long-term adverse effects in the aquatic environment.

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

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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

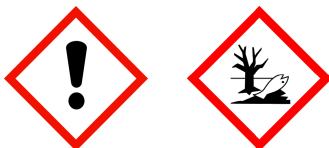
Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements:

Causes skin irritation.

Causes serious eye irritation.

Toxic 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.

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Additional advice on labelling

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact

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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 | | | 25 - < 30 % |
| | 276-957-5 | | | |
| | Skin Irrit. 2, Eye Irrit. 2; H315 H319 | | | |
| 131-17-9 | diallyl phthalate | | | 10 - < 15 % |
| | 205-016-3 | 607-086-00-4 | | |
| | Acute Tox. 4, Aquatic Acute 1, Aquatic Chronic 1; H302 H400 H410 | | | |
| 3290-92-4 | TMPTMA | | | 1 - < 5 % |
| | 221-950-4 | | 01-2119542176-41 | |
| | Aquatic Chronic 2; H411 | | | |

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 - 23 °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 |
|----------|-------------------|-----|-------------------|-----------|---------------|--------|
| 131-17-9 | Diallyl phthalate | - | 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.

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): 1.7 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.

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10.4. Conditions to avoid

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 |
| 131-17-9 | diallyl phthalate | | | | |
| | oral | ATE 500 mg/kg | | | |
| 3290-92-4 | TMPTMA | | | | |
| | oral | LD50 > 5000 mg/kg | Rat | literature value | |
| | dermal | LD50 > 3000 mg/kg | Rabbit | literature value | |

Irritation and corrosivity

Causes skin irritation.

Causes serious eye 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 |
| 3290-92-4 | TMPTMA | | | | | |
| | 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 | | |

12.3. Bioaccumulative potential**Partition coefficient n-octanol/water**

| CAS No | Chemical name | Log Pow |
|-----------|---------------|---------|
| 3290-92-4 | TMPTMA | 3.53 |

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

according to Regulation (EC) No 1907/2006

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Land transport (ADR/RID)

| | |
|--|--|
| 14.1. UN number: | UN 3082 |
| 14.2. UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Diallyl phthalate) |
| 14.3. Transport hazard class(es): | 9 |
| 14.4. Packing group: | III |
| Hazard label: | 9 |
| Classification code: | M6 |
| Special Provisions: | 274 335 601 |
| Limited quantity: | 5 L |
| Excepted quantity: | E1 |
| Transport category: | 3 |
| Hazard No: | 90 |
| Tunnel restriction code: | E |

Marine transport (IMDG)

| | |
|--|--|
| 14.1. UN number: | UN 3082 |
| 14.2. UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Diallyl phthalate) |
| 14.3. Transport hazard class(es): | 9 |
| 14.4. Packing group: | III |
| Hazard label: | 9 |
| Special Provisions: | 274, 335 |
| Limited quantity: | 5 L |
| Excepted quantity: | E1 |
| EmS: | F-A, S-F |

Air transport (ICAO-TI/IATA-DGR)

| | |
|--|--|
| 14.1. UN number: | UN 3082 |
| 14.2. UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Diallyl phthalate) |
| 14.3. Transport hazard class(es): | 9 |
| 14.4. Packing group: | III |
| Hazard label: | 9 |
| Special Provisions: | A97 A158 |
| Limited quantity Passenger: | 30 kg G |
| Passenger LQ: | Y964 |
| Excepted quantity: | E1 |
| IATA-packing instructions - Passenger: | 964 |
| IATA-max. quantity - Passenger: | 450 L |
| IATA-packing instructions - Cargo: | 964 |
| IATA-max. quantity - Cargo: | 450 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

according to Regulation (EC) No 1907/2006

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Relevant H and EUH statements (number and full text)

| | |
|------|---|
| H302 | Harmful if swallowed. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | Toxic to aquatic life with long lasting effects. |

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.)