

according to Regulation (EC) No 1907/2006

Cool Temp natural

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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 +41 (71) 75 75 300 Telephone: 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

Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements: Causes skin irritation. Causes serious eye irritation.

T : (...

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 | | | | | |
|------------|------------------------------------------------------------------|-------------------------------|------------------|--|--|--|
| | EC No | Index No | REACH No | | | |
| | Classification according to Regula | .ion (EC) No. 1272/2008 [CLP] | • | | | |
| 72869-86-4 | UDMA | | | | | |
| | 276-957-5 | | | | | |
| | Skin Irrit. 2, Eye Irrit. 2; H315 H319 | | | | | |
| 131-17-9 | diallyl phthalate | | | | | |
| | 205-016-3 | 607-086-00-4 | | | | |
| | Acute Tox. 4, Aquatic Acute 1, Aquatic Chronic 1; H302 H400 H410 | | | | | |
| 3290-92-4 | TMPTMA | | | | | |
| | 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



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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/m³ | 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):

Water solubility:

(at 23 °C)

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 mg/kg | 500 | | | |
| 3290-92-4 | ТМРТМА | | | | | |
| | oral | LD50 mg/kg | > 5000 | Rat | literature value | |
| | dermal | LD50 mg/kg | > 3000 | 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 | ТМРТМА | | | | | | |
| | Acute fish toxicity | LC50 | 2 mg/l | 96 h | Oncorhynchus mykiss | literature value | |
| | Acute algae toxicity | ErC50 mg/l | 0.177 | | Pseudokirchneriella subcapitata | literature value | |
| | Acute crustacea toxicity | EC50 mg/l | > 9.22 | 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



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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 phtalate)

14.3. Transport hazard class(es):914.4. Packing group:IIIHazard label:9Classification 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)

<u>14.1. UN number:</u> UN 3082

14.2. UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(Diallyl phtalate)

14.3. Transport hazard class(es):914.4. Packing group:IIIHazard label:9Special Provisions:274, 335Limited quantity:5 LExcepted quantity:E1

Air transport (ICAO-TI/IATA-DGR)

EmS:

14.1. UN number: UN 3082

14.2. UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(Diallyl phtalate)

F-A, S-F

14.3. Transport hazard class(es):914.4. Packing group:IIIHazard label:9

Special Provisions:

Limited quantity Passenger:

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



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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 lo |

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.)