

SAFETY DATA SHEETS

This SDS packet was issued with item:

070610295

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).

070610261

according to Regulation (EC) No 1907/2006

SoloCem Base_Catalyst

Revision date: 28.04.2015

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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: | 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 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**

TEGDMA

4-META

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.

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- 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 | EC No | Index No | REACH No | Quantity |
|------------|---|---|--------------|----------|------------|
| | | Classification according to Regulation (EC) No. 1272/2008 [CLP] | | | |
| 72869-86-4 | UDMA | | | | 5 - < 10 % |
| | 276-957-5 | | | | |
| | Aquatic Chronic 3; H412 | | | | |
| 109-16-0 | TEGDMA | | | | 5 - < 10 % |
| | 203-652-6 | | | | |
| | Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335 | | | | |
| 70293-55-9 | 4-META | | | | 5 - < 10 % |
| | 274-547-0 | | | | |
| | Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H302 H315 H319 H317 | | | | |
| 868-77-9 | 2-hydroxyethyl methacrylate | | | | 1 - < 5 % |
| | 212-782-2 | | 607-124-00-X | | |
| | Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1; H319 H315 H317 | | | | |
| 1314-13-2 | Zinc oxide coated | | | | 1 - < 5 % |
| | 215-222-5 | | | | |
| | Skin Irrit. 3, Eye Irrit. 2B, Aquatic Acute 1 (M-Factor = 10); H316 H320 H400 | | | | |
| 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 | | | | |

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**

according to Regulation (EC) No 1907/2006

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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.

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Paste

Colour:

off-white

Test method

according to Regulation (EC) No 1907/2006

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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**10.4. 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 |
| 72869-86-4 | UDMA | | | |
| | oral | LD50 >2000 mg/kg | Rat | OECD 401 |
| 109-16-0 | TEGDMA | | | |
| | oral | LD50 10837 mg/kg | Rat | literature value |
| 70293-55-9 | 4-META | | | |
| | oral | LD50 987 mg/kg | Rat | Manufacturer. |
| 868-77-9 | 2-hydroxyethyl methacrylate | | | |
| | oral | LD50 5050 mg/kg | Rat | |
| 1314-13-2 | Zinc oxide coated | | | |
| | oral | LD50 7950 mg/kg | Mouse. | literature value |

Irritation and corrosivity

Causes skin irritation.
 Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (TEGDMA), (4-META), (2-hydroxyethyl methacrylate)

SECTION 12: Ecological information**12.1. Toxicity**

according to Regulation (EC) No 1907/2006

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| CAS No | Chemical name | | | | |
|------------|-----------------------------|------|------------|---------|---|
| | Aquatic toxicity | Dose | [h] [d] | Species | Source |
| 72869-86-4 | UDMA | | | | |
| | Acute fish toxicity | LC50 | 10.1 mg/l | 96 h | Brachydanio rerio (zebra-fish) OECD 203 |
| 868-77-9 | 2-hydroxyethyl methacrylate | | | | |
| | Acute fish toxicity | LC50 | 227 mg/l | 96 h | Pimephales promelas |
| 1314-13-2 | Zinc oxide coated | | | | |
| | Acute fish toxicity | LC50 | 1.1 mg/l | 96 h | Oncorhynchus mykiss (Rainbow trout) literature value |
| | Acute crustacea toxicity | EC50 | 0.098 mg/l | 48 h | Daphnia magna literature value |

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 |
| 109-16-0 | TEGDMA | 1.88 |
| 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)

14.1. UN number: ---

Other applicable information

Not a hazardous material with respect to these transportation regulations.

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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****SECTION 16: Other information****Relevant H and EUH statements (number and full text)**

| | |
|------|--|
| H241 | Heating may cause a fire or explosion. |
| H302 | Harmful if swallowed. |
| H315 | Causes skin irritation. |
| H316 | Causes mild skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H320 | Causes eye irritation. |
| H335 | May cause respiratory irritation. |
| H400 | Very toxic to aquatic life. |
| H412 | Harmful 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.)