

SAFETY DATA SHEETS

This SDS packet was issued with item:

077184666

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).

077184658 077184674

Speedex Universal Activator

Revision date : 06.05.2010

Print date : 06.05.2010

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

Speedex Universal Activator

Use of the substance/preparation

Activator.

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

Further Information

Only supplied to dentists and dental laboratories or upon their instructions

2. Hazards identification**Classification**

Indications of danger : Harmful, Irritant

R-phrases :

Flammable.

Risk of serious damage to eyes.

Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.

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 |
|--------|---------|----------------------------|-----------|---------------------------------|
| | | Alkyl silicates | 20 - 25 % | Xn, Xi R10-20-37/38-41-48/22-53 |
| | | Diocetyl tin dicarboxylate | 5 - 10 % | Xn R48/22-53 |

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.

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5. Fire-fighting measures**Suitable extinguishing media**Water. Foam. Extinguishing powder. Carbon dioxide (CO₂). Sand.**Additional information**

Extinguishing materials should be selected according to the surrounding area.

6. Accidental release measures**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.

Further information on handling

After use replace the closing cap immediately.

Storage**Further information on storage conditions**

Keep the packing dry and well sealed to prevent contamination and absorption of dampness.

Recommended storage temperature: 15 - 23 °C

8. Exposure controls/personal protection**Exposure limit values****Exposure controls****Protective and hygiene measures**

When using do not eat, drink or smoke.

Hand protection

Single-use gloves.

Eye protection

Framed glasses.

Skin protection

Lab apron.

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

| | |
|------------------|----------------|
| Physical state : | Paste |
| Colour : | green |
| Odour : | characteristic |

Important health, safety and environmental information

Test method

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Changes in the physical state

| | |
|--------------------------------|-----------------------|
| Boiling point : | >150 °C |
| Density (at 23 °C) : | 1.1 g/cm ³ |
| Water solubility (at 23 °C) : | insoluble |
| Solubility in other solvents : | ketone. |

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

Air, humid.

Additional information

Keep the packing dry and well sealed to prevent contamination and absorption of dampness.

11. Toxicological information**Acute toxicity**

LD50: >2000 mg/kg (Rat.)

The statement is derived from products of similar composition.

Corrosive and irritant effects

Irritant effect on the skin: (Rabbit.)

Not an irritant.

The statement is derived from products of similar composition.

Sensitising effects

Guinea-pig.

no danger of sensitization.

The statement is derived from products of similar composition.

12. Ecological information**Further information**

May cause long-term adverse effects in the aquatic environment.

Do not allow uncontrolled leakage of product into the environment.

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**Further Information**

Not a hazardous material with respect to these transportation regulations.

15. Regulatory information**Labelling**

Danger symbols : Xn - Harmful

Hazardous component(s) to be indicated on label

Alkyl silicates

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R phrases

- 10 Flammable.
- 41 Risk of serious damage to eyes.
- 48/20/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
- 53 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.
- 61 Avoid release to the environment. Refer to special instructions / Safety data sheets.
- 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

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

- 10 Flammable.
- 20 Harmful by inhalation.
- 37/38 Irritating to respiratory system and skin.
- 41 Risk of serious damage to eyes.
- 48/20/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
- 48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed.
- 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**

Activator.

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)

Further Information

Only supplied to dentists and dental laboratories or upon their instructions

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Acute toxicity: Acute Tox. 4

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Specific target organ toxicity - repeated exposure: STOT RE 2

Hazard Statements:

Harmful if inhaled.

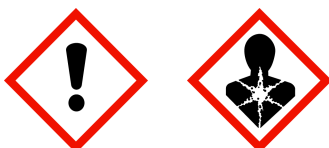
Causes skin irritation.

Causes serious eye irritation.

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements**Regulation (EC) No. 1272/2008****Hazard components for labelling**

Alkyl silicates

Signal word: Warning**Pictograms:****Hazard statements**

H315

Causes skin irritation.

H319

Causes serious eye irritation.

H332

Harmful if inhaled.

H373

May cause damage to organs through prolonged or repeated exposure.

according to Regulation (EC) No 1907/2006

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Precautionary statements

| | |
|----------------|--|
| P202 | Do not handle until all safety precautions have been read and understood. |
| 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. |
| P337+P313 | If eye irritation persists: Get medical advice/attention. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P332+P313 | If skin irritation occurs: Get medical advice/attention. |
| P260 | Do not breathe dust/fume/gas/mist/vapours/spray. |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P314 | Get medical advice/attention if you feel unwell. |

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 | Quantity |
|------------|---|-------------|
| | EC No | |
| | Index No | |
| | REACH No | |
| | GHS Classification | |
| | Alkyl silicates | 15 - < 20 % |
| | Flam. Liq. 3, Acute Tox. 3, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, STOT RE 2, Aquatic Chronic 4; H226 H331 H315 H319 H335 H373 H413 | |
| 68299-15-0 | Dioctyltindinedecanoate | 5 - < 10 % |
| | 269-595-4 | |
| | STOT SE 2; H371 | |

Full text of H and EUH statements: see section 16.

Further Information

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SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

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 mediaWater. Foam. Extinguishing powder. Carbon dioxide (CO₂). Sand.**Additional information**

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures**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**

The product is intended for professional use.

Avoid contact with skin and eyes.

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**

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

Recommended storage temperature: 15 - 23 °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

Eye glasses with side protection

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Hand protection

Suitable material: When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Disposable gloves - Suitable material: NBR (Nitrile rubber).

*

Skin protection

Wear suitable protective clothing.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|-----------------|----------------|
| Physical state: | Paste |
| Colour: | green |
| Odour: | characteristic |

Test method

according to Regulation (EC) No 1907/2006

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Changes in the physical state

Initial boiling point and boiling range: >150 °C

Density (at 23 °C): 1.1 g/cm³Water solubility:
(at 23 °C) insoluble

Solubility in other solvents

ketone.

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

Air, humid.

Further information

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Harmful if inhaled.

LD50: >2000 mg/kg (Rat)

The statement is derived from products of similar composition.

ATEmix calculated

ATE (inhalation vapour) 15.38 mg/l; ATE (inhalation aerosol) 2.564 mg/l

| CAS No | Chemical name | | | | |
|--------|--------------------|--------------|---------|--------|--------|
| | Exposure route | Dose | Species | Source | Method |
| | Alkyl silicates | | | | |
| | inhalation vapour | ATE 3 mg/l | | | |
| | inhalation aerosol | ATE 0,5 mg/l | | | |

Irritation and corrosivity

Causes serious eye irritation.

Irritant effect on the skin: (Rabbit)

Not an irritant.

The statement is derived from products of similar composition.

Sensitising effects

Guinea-pig.

no danger of sensitization.

The statement is derived from products of similar composition.

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard

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

according to Regulation (EC) No 1907/2006

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SECTION 12: Ecological information**Further information**

Avoid release to the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Advice on disposal**

Dispose of waste according to applicable legislation.

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number:** -----**Other applicable information (land transport)**

No dangerous good in sense of these transport regulations.

Marine transport (IMDG)**14.1. UN number:** -----**Other applicable information (marine transport)**

No dangerous good in sense of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)**14.1. UN number:** -----**Other applicable information (air transport)**

No dangerous good in sense of these transport regulations.

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**Changes**

* Data changed compared with the previous version

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%

according to Regulation (EC) No 1907/2006

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Relevant H and EUH statements (number and full text)

| | |
|------|--|
| H226 | Flammable liquid and vapour. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H331 | Toxic if inhaled. |
| H332 | Harmful if inhaled. |
| H335 | May cause respiratory irritation. |
| H371 | May cause damage to organs (immune system) if swallowed. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H413 | May cause long lasting harmful effects to aquatic life. |

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.

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