

according to Regulation (EC) No 1907/2006

Speedex Universal Activator

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Speedex Universal Activator

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 www.coltene.com Internet: Responsible Department: Regulatory Affairs msds@coltene.com

1.4. Emergency telephone

+41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

number:

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.



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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	Dioctyltindineodecanoate			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



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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

6.2. 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 absorbtion 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



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Changes in the physical state

Initial boiling point and boiling range: >150 °C

Density (at 23 °C): 1.1 g/cm³

Water solubility: insoluble

Solubility in other solvents

ketone.

(at 23 °C)

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 absorbtion 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.



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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%

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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.
11440	

Further Information

H413

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.

May cause long lasting harmful effects to aquatic life.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)