

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: 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 +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:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Specific target organ toxicity - single exposure: STOT SE 3 Specific target organ toxicity - repeated exposure: STOT RE 2 Hazardous to the aquatic environment: Aquatic Chronic 4

Hazard Statements:
Causes skin irritation.
Causes serious eye irritation.
May cause respiratory irritation.

May cause damage to organs through prolonged or repeated exposure.

May cause long lasting harmful effects to aquatic life $\!.$

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.



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H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements

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

P302+P352 IF ON SKIN: Wash with plenty of water.

P332+P313 If skin irritation 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.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P314 Get medical advice/attention if you feel unwell.

P273 Avoid release to the environment.

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		
	Classification according to Regulation (EC) No. 1272/2008 [CLP]				
	Alkyl silicates			20 - < 25 %	
	Flam. Liq. 3, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, STOT RE 2, Aquatic Chronic 4; H226 H332 H315 H319 H335 H373 H413				
24577-34-2	Dioctyltin dicarboxylate			5 - < 10 %	
	246-325-3				
	STOT RE 2, Aquatic Chronic 4; H373 H413				

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.



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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

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

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: green
Odour: characteristic

Test method

Changes in the physical state

Initial boiling point and boiling range: >150 °C

Density (at 23 °C): 1.1 g/cm³

Water solubility: insoluble (at 23 °C)

Solubility in other solvents

ketone.

SECTION 10: Stability and reactivity



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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

LD50: >2000 mg/kg (Rat)

The statement is derived from products of similar composition.

CAS No	Chemical name				
	Exposure route	Dose		Species	Source
	Alkyl silicates				
	inhalative vapour	ATE	11 mg/l		
	inhalative aerosol	ATE	1,5 mg/l		
24577-34-2	Dioctyltin dicarboxylate				
	oral	LD50	2764 mg/kg	Rat	
	dermal	LD50	2764 mg/kg	Rabbit	

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.

STOT-single exposure

May cause respiratory irritation.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

SECTION 12: Ecological information

12.1. Toxicity

CAS No	Chemical name					
	Aquatic toxicity	Dose		[h] [d]	Species	Source
24577-34-2	Dioctyltin dicarboxylate					
	Acute fish toxicity	LC50	22.8 mg/l	96 h		
	Acute crustacea toxicity	EC50	12.2 mg/l	48 h	Daphnia magna	

Further information

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

Do not allow uncontrolled leakage of product into the environment.



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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: ------

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.

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

Relevant H and EUH statements (number and full text)

Flammable liquid and	vapour.
	Flammable liquid and

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

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.

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