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Page 1/7

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 28.03.2023 Version number 1 Revision: 28.03.2023

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

- · Product identifier
- · Trade name: Cavex SiliconA Bite Catalyst
- · Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture For dental purposes.
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Cavex Holland B.V.

Fustweg 5

2031 CJ Haarlem

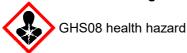
The Netherlands

T +31 23 530 7700 E-Mail : dental@cavex.nl

- F +31 23 535 6482 Website: www.cavex.nl
- · Further information obtainable from: Product safety department
- Emergency telephone number: During normal opening times: +31 23 530 7700

2 Hazards identification

- · Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



GHS08

- · Signal word Danger
- · Hazard-determining components of labelling:

cristobalite

- · Hazard statements
- H372 Causes damage to organs through prolonged or repeated exposure.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read carefully and follow all instructions.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P314 Get medical advice/attention if you feel unwell.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 28.03.2023 Version number 1 Revision: 28.03.2023

Trade name: Cavex SiliconA Bite Catalyst

(Contd. of page 1)

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.
- · Dangerous components:

CAS: 14464-46-1 cristobalite

50-70%

EINECS: 238-455-4 **STOT RE 1, H372**

CAS: 68083-19-2 Polydimethylsiloxane, vinyl-terminated

20-40%

Skin Irrit. 2, H315; Eye Irrit. 2, H319

· Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · Description of first aid measures
- · General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gases are produced.

- Advice for firefighters
- · Protective equipment: Mouth respiratory protective device.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Mount respiratory protective device.

Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Dilute with plenty of water.

Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· Information about fire - and explosion protection: Keep respiratory protective device available.

(Contd. on page 3)

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 28.03.2023 Version number 1 Revision: 28.03.2023

Trade name: Cavex SiliconA Bite Catalyst

(Contd. of page 2)

- · Conditions for safe storage, including any incompatibilities
- Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

14464-46-1 cristobalite

OEL Long-term value: 0.1 mg/m³

- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Appropriate engineering controls No further data: see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Hand protection



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection



Tightly sealed goggles

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information

· Physical state Fluid · Colour: White

Odour: Characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: Undetermined.

Boiling point or initial boiling point and boiling

range 2,230 °C

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 28.03.2023 Version number 1 Revision: 28.03.2023

Trade name: Cavex SiliconA Bite Catalyst

(Contd. of page 3)

· Flammability Not applicable.

· Lower and upper explosion limit

· Lower: 2.6 Vol % 13 Vol % · Upper: · Flash point: >130 °C · Auto-ignition temperature: >370 °C

· Decomposition temperature: Not determined. Not determined.

· Viscosity:

· Kinematic viscosity Not determined.

· Kinematic viscosity

· Dynamic: Not determined.

·Solubility

· water: Fully miscible. Partition coefficient n-octanol/water (log value) Not determined.

233 hPa · Vapour pressure at 20 °C:

· Vapour pressure:

· Density and/or relative density

· Density at 20 °C: 1.5 g/cm³ · Relative density Not determined. · Vapour density Not determined.

· Other information

· Appearance:

· Form: Fluid

· Important information on protection of health and environment, and on safety.

· Ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

Void

Void

· Solvent content:

· VOC (EC) 0.00 %

· Change in condition

· Evaporation rate Not determined.

· Information with regard to physical hazard classes

· Explosives Void Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void Pyrophoric liquids Void · Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable gases in contact with water Void · Oxidising liquids Void · Oxidising solids Void · Organic peroxides Void · Corrosive to metals

10 Stability and reactivity

· Desensitised explosives

- · Reactivity No further relevant information available.
- · Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 28.03.2023 Version number 1 Revision: 28.03.2023

Trade name: Cavex SiliconA Bite Catalyst

(Contd. of page 4)

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect: -
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity 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 Causes damage to organs through prolonged or repeated exposure.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- Other adverse effects
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Not hazardous for water.

Harmful to aquatic organisms

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

· UN number or ID number

· ADR, ADN, IMDG, IATA not regulated

· UN proper shipping name

· ADR, ADN, IMDG, IATA not regulated

(Contd. on page 6)

Safety data sheet according to 1907/2006/EC, Article 31

Version number 1 Revision: 28.03.2023 Printing date 28.03.2023

Trade name: Cavex SiliconA Bite Catalyst

(Contd. of page 5)

Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class not regulated

Packing group

· ADR, IMDG, IATA not regulated · Environmental hazards: Not applicable. · Special precautions for user Not applicable.

· Maritime transport in bulk according to IMO

instruments Not applicable. · UN "Model Regulation": not regulated

15 Regulatory information

- · Directive 2004/42/EC
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

None of the ingredients is listed.

- REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H372 Causes damage to organs through prolonged or repeated exposure.

- · Department issuing SDS: Product safety department
- · Contact: .
- Abbreviations and acronyms:

ADR: Accord relatif au transport international 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 Harmonised 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 (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation - Category 2

Eye Irrit. 2: Serious eye damage/eye irritation - Category 2

Page 7/7

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 28.03.2023 Version number 1 Revision: 28.03.2023

Trade name: Cavex SiliconA Bite Catalyst

(Contd. of page 6)

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3