

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 17.03.2023

Version number 1

Revision: 17.03.2023

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

- **Product identifier**
- **Trade name: Cavex Outline - White**
- **UFI: N830-00FM-400C-UPW8**
- **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**



GHS09 environment

Aquatic Acute 1 H400 Very toxic to aquatic life.  
 Aquatic Chronic 1 H410 Very toxic 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**



GHS09

- **Signal word** Warning
- **Hazard statements**  
H410 Very toxic 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.  
P273 Avoid release to the environment.  
P391 Collect spillage.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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### 3 Composition/information on ingredients

- **Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 1314-13-2    zinc oxide     Aquatic Acute 1, H400; Aquatic Chronic 1, H410    40-60%  
EINECS: 215-222-5

CAS: 1309-48-4    magnesium oxide    substance with a Community workplace exposure limit    20-40%  
EINECS: 215-171-9

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

### 4 First aid measures

- **Description of first aid measures**

- **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** No further relevant information available.

- **Advice for firefighters**

- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.

- **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.

- **Methods and material for containment and cleaning up:**

Dispose contaminated material as waste according to section 13.

- **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** No special precautions are necessary if used correctly.

- **Information about fire - and explosion protection:** No special measures required.

- **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.

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### 8 Exposure controls/personal protection

- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

- 1314-13-2 zinc oxide**

- OEL Short-term value: 10 mg/m<sup>3</sup>

- Long-term value: 2\* mg/m<sup>3</sup>

- \*respirable fraction

- 1309-48-4 magnesium oxide**

- OEL Short-term value: 10\*\* mg/m<sup>3</sup>

- Long-term value: 4\* 5\*\* 10\*\*\* mg/m<sup>3</sup>

- \*respirable dust \*\*fume \*\*\*total inhalable dust

- **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:** Wash hands before breaks and at the end of work.

- **Respiratory protection:** Not required.

- **Hand protection**

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** Not required.

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Physical state**

Solid

- **Colour:**

Whitish

- **Odour:**

Odourless

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

Undetermined.

- **Boiling point or initial boiling point and boiling range**

100 °C

- **Flammability**

Not determined.

- **Lower and upper explosion limit**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Flash point:**

210 °C

- **Decomposition temperature:**

Not determined.

- **pH**

Not applicable.

- **Viscosity:**

- **Kinematic viscosity**

Not applicable.

- **Dynamic:**

Not applicable.

- **Solubility**

- **water:**

Insoluble.

- **Partition coefficient n-octanol/water (log value)** Not determined.

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· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density at 20 °C:	1.08 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not applicable.
· Particle characteristics	See section 3.
· Other information	
· Appearance:	
· Form:	Pasty
· 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.
· Solvent content:	
· Solids content:	28.0 %
· Change in condition	
· Evaporation rate	Not applicable.
· 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	Void
· Desensitised explosives	Void

## 10 Stability and reactivity

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

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- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Information on other hazards**
- **Endocrine disrupting properties**  
128-37-0 Butylated hydroxytoluene

List II



## 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** For information on endocrine disrupting properties see section 11.
- **Other adverse effects**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**  
Not hazardous for water.  
Also poisonous for fish and plankton in water bodies.  
Very toxic for 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.

## 14 Transport information

- **UN number or ID number**
- **ADR, IMDG, IATA** UN3077
- **UN proper shipping name**
- **ADR** 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
- **IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT
- **IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
- **Transport hazard class(es)**
- **ADR, IMDG, IATA**
-  
- **Class** 9 Miscellaneous dangerous substances and articles.
- **Label** 9
- **Packing group**
- **ADR, IMDG, IATA** III
- **Environmental hazards:**
- **Marine pollutant:** Symbol (fish and tree)

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· <b>Special marking (ADR):</b>	Symbol (fish and tree)
· <b>Special marking (IATA):</b>	Symbol (fish and tree)
· <b>Special precautions for user</b>	Not applicable.
· <b>Hazard identification number (Kemler code):</b>	90
· <b>EMS Number:</b>	F-A,S-F
· <b>Stowage Category</b>	A
· <b>Stowage Code</b>	SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.
· <b>Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	5 kg Attention: Special provisions A197 IATA , 375 ADR and / or IMDG Code Section 2.10.2.7 can be applied during transport.
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· <b>Transport category</b>	3
· <b>Tunnel restriction code</b>	(-)
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· <b>UN "Model Regulation":</b>	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE), 9, III

## 15 Regulatory information

- **Directive 2004/42/EC**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category** E1 Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **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.

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### 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**

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

· **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1