

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 16.03.2023

Version number 2 (replaces version 1)

Revision: 16.03.2023

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

- **Product identifier**
- **Trade name: Cavex Orthotrace**
- **UFI:** KU50-605H-A006-PXD6
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Impression material 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**
The product is not classified, according to the CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
Safety data sheet available on request.
- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **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: 68855-54-9	Kieselguhr, soda ash flux-calcined	50-70%
EINECS: 272-489-0	substance with a Community workplace exposure limit	
CAS: 14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	2.5-7.5%
EINECS: 238-877-9	substance with a Community workplace exposure limit	
CAS: 16919-27-0	dipotassium hexafluorotitanate	≥1-≤2.5%
EINECS: 240-969-9	☠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; STOT SE 3, H335	
CAS: 1309-48-4	magnesium oxide	≤2.5%
EINECS: 215-171-9	substance with a Community workplace exposure limit	
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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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 to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.

8 Exposure controls/personal protection

- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
68855-54-9 Kieselguhr, soda ash flux-calcined
OEL Long-term value: 1.2 mg/m³
- **14807-96-6 Talc (Mg₃H₂(SiO₃)₄)**
OEL Long-term value: 10* 0.8** mg/m³
*total inhalable **respirable dust
- **1309-48-4 magnesium oxide**
OEL Short-term value: 10** mg/m³
Long-term value: 4* 5** 10*** mg/m³
*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.

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· 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:

Pink

· Odour:

Sweetish

· Odour threshold:

Not determined.

· Melting point/freezing point:

Undetermined.

· Boiling point or initial boiling point and boiling range

Undetermined.

· Flammability

Not determined.

· Lower and upper explosion limit**· Lower:**

Not determined.

· Upper:

Not determined.

· Flash point:

Not applicable.

· 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.

· Vapour pressure:

Not applicable.

· Density and/or relative density**· Density:**

Not determined.

· Relative density

Not determined.

· Vapour density

Not applicable.

· Particle characteristics

See section 3.

· Other information**· Appearance:****· Form:**

Powder

· 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:**

100.0 %

· Change in condition**· Evaporation rate**

Not applicable.

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· 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.
- **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**
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.

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- **Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

- **Other adverse effects**

- **Additional ecological information:**

- **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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, ADN, IMDG, IATA** not regulated

- **UN proper shipping name**

- **ADR, ADN, IMDG, IATA** not regulated

- **Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA** not regulated

- **Class**

- **Packing group** not regulated

- **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.

- **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.

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- **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**

H302 Harmful if swallowed.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.

- **Department issuing SDS:** Product safety department

- **Contact:** .

- **Version number of previous version:** 1

- **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
Acute Tox. 4: Acute toxicity – Category 4
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3