

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

Printing date 10.04.2020

Revision: 10.04.2020

### 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** Dental impression material.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Cavex Holland B.V.  
Fustweg 5  
2031 CJ Haarlem  
T +31 23 530 7700 E-Mail : dental@cavex.nl  
The Netherlands  
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

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

· **Dangerous components:**

CAS: 14807-96-6 EINECS: 238-877-9	Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> ) substance with a Community workplace exposure limit	2.5-7.5%
CAS: 16919-27-0 EINECS: 240-969-9	dipotassium hexafluorotitanate Eye Dam. 1, H318; Acute Tox. 4, H302; STOT SE 3, H335	≥1-≤2.5%
CAS: 1309-48-4 EINECS: 215-171-9	magnesium oxide substance with a Community workplace exposure limit	≤2.5%

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· **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.
- **Information for 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

- **Handling:**
- **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

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

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

14807-96-6 Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>)

WEL Long-term value: 1 mg/m<sup>3</sup>

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**1309-48-4 magnesium oxide**

WEL Long-term value:  $10^{-4}$  mg/m<sup>3</sup>  
(as Mg) \*inhalable dust \*\*fume and respirable dust

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:**  
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 protection:** Not required.

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Powder
Colour:	Pink
Odour:	Sweetish
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.

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· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>Solids content:</b>	100.0 %
· <b>Other information</b>	No further relevant information available.

### 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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

**16919-27-0 dipotassium hexafluorotitanate**

Oral	LD50	324 mg/kg (rat) (LDL50)
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- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

### 12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

**16919-27-0 dipotassium hexafluorotitanate**

EC50	48.2 mg/kg (daphnia)
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- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 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

- |   |                 |
|---|-----------------|
| · <b>UN-Number</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   | not regulated   |
| · <b>UN proper shipping name</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   | not regulated   |
| · <b>Transport hazard class(es)</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | not regulated   |
| · <b>Packing group</b>  |                 |
| · <b>ADR, IMDG, IATA</b>  | not regulated   |
| · <b>Environmental hazards:</b>   | Not applicable. |
| · <b>Special precautions for user</b>                                       | Not applicable. |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>   | not regulated   |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** 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**  
H302 Harmful if swallowed.  
H318 Causes serious eye damage.

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*H335 May cause respiratory irritation.*

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

· **Contact:** .

· **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 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)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Acute Tox. 4: Acute toxicity - oral – Category 4*

*Eye Dam. 1: Serious eye damage/eye irritation – Category 1*

*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*

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