

## Safety data sheet

### according to Regulation (EC) No 1907/2006, Article 31

Printing date 20.07.2026

Version number 1

Revision: 15.07.2026

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

- **Product identifier**
- **Trade name:** Cavex Orthotrace
- **UFI:** HNV0-R0GC-300W-PNDK
- **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:**  
Cavex product safety department:  
Dental@cavex.nl
- **Emergency telephone number:**  
Cavex Holland BV  
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
- **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: 9005-36-1    | dipotassium                                                                                            | ≥10-≤15% |
|                   |  Eye Irrit. 2, H319 |          |
| CAS: 10101-41-4   | calcium sulfate dihydrate                                                                              | 2.5-10%  |
|                   | substance with a Community workplace exposure limit                                                    |          |
| CAS: 14807-96-6   | Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )                                | 2.5-7.5% |
| EINECS: 238-877-9 | substance with a Community workplace exposure limit                                                    |          |
| CAS: 1309-48-4    | magnesium oxide                                                                                        | ≤2.5%    |
| EINECS: 215-171-9 | substance with a Community workplace exposure limit                                                    |          |

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CAS: 16919-27-0 dipotassium hexafluorotitanate  
 EINECS: 240-969-9  Eye Dam. 1, H318;  Acute Tox. 4, H302; STOT SE 3, H335  
 CAS: 13463-67-7 titanium dioxide  
 EINECS: 236-675-5 substance with a Community workplace exposure limit

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≥1-≤2.5%

≤2.5%

· **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:** No special measures required.
- **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 measures required.
- **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:**
  - 10101-41-4 calcium sulfate dihydrate**  
OEL Long-term value: 10\* 4\*\* mg/m<sup>3</sup>  
\*inhalable dust, \*\*respirable dust
  - 14807-96-6 Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>)**  
OEL Long-term value: 10\* 0.8\*\* mg/m<sup>3</sup>  
\*total inhalable \*\*respirable dust
  - 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

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**13463-67-7 titanium dioxide**OEL Long-term value: 10\* 4\*\* mg/m<sup>3</sup>

\*total inhalable \*\*respirable 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:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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:** 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** Mixture reacts violently with water.
- **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.

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|                                                                                        |                                               |
|----------------------------------------------------------------------------------------|-----------------------------------------------|
| · <b>Other information</b>                                                             |                                               |
| · <b>Appearance:</b>                                                                   |                                               |
| · <b>Form:</b>                                                                         | Powder                                        |
| · <b>Important information on protection of health and environment, and on safety.</b> |                                               |
| · <b>Ignition temperature:</b>                                                         | Product is not selfigniting.                  |
| · <b>Explosive properties:</b>                                                         | Product does not present an explosion hazard. |
| · <b>Solvent content:</b>                                                              |                                               |
| · <b>Solids content:</b>                                                               | 100.0 %                                       |
| · <b>Change in condition</b>                                                           |                                               |
| · <b>Evaporation rate</b>                                                              | Not applicable.                               |
| · <b>Information with regard to physical hazard classes</b>                            |                                               |
| · <b>Explosives</b>                                                                    | Void                                          |
| · <b>Flammable gases</b>                                                               | Void                                          |
| · <b>Aerosols</b>                                                                      | Void                                          |
| · <b>Oxidising gases</b>                                                               | Void                                          |
| · <b>Gases under pressure</b>                                                          | Void                                          |
| · <b>Flammable liquids</b>                                                             | Void                                          |
| · <b>Flammable solids</b>                                                              | Void                                          |
| · <b>Self-reactive substances and mixtures</b>                                         | Void                                          |
| · <b>Pyrophoric liquids</b>                                                            | Void                                          |
| · <b>Pyrophoric solids</b>                                                             | Void                                          |
| · <b>Self-heating substances and mixtures</b>                                          | Void                                          |
| · <b>Substances and mixtures, which emit flammable gases in contact with water</b>     | Void                                          |
| · <b>Oxidising liquids</b>                                                             | Void                                          |
| · <b>Oxidising solids</b>                                                              | Void                                          |
| · <b>Organic peroxides</b>                                                             | Void                                          |
| · <b>Corrosive to metals</b>                                                           | Void                                          |
| · <b>Desensitised explosives</b>                                                       | 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.

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- **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**
- **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** Smaller quantities can be disposed of with household waste.
- **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**
- **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.
- **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.

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- **REGULATION (EU) 2019/1148**
- **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**

H302 Harmful if swallowed.  
H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

- **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  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3