

Safety data sheet

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

Printing date 07.04.2026

Version number 1

Revision: 04.03.2026

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:** 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 ⚠ Eye Irrit. 2, H319	≥10-≤15%
CAS: 10101-41-4	calcium sulfate dihydrate substance with a Community workplace exposure limit	2.5-10%
CAS: 14807-96-6 EINECS: 238-877-9	Talc (Mg ₃ H ₂ (SiO ₃) ₄) substance with a Community workplace exposure limit	2.5-7.5%
CAS: 1309-48-4 EINECS: 215-171-9	magnesium oxide substance with a Community workplace exposure limit	≤2.5%
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%

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CAS: 13463-67-7 titanium dioxide
 EINECS: 236-675-5 substance with a Community workplace exposure limit

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 ≤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/m³
 *inhalable dust, **respirable dust
 - 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

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13463-67-7 titanium dioxide

OEL Long-term value: 10* 4** mg/m³
 *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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· 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.
· 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.

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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.
- **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
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