

SAFETY DATA SHEETS

This SDS packet was issued with item:

072346005

N/A

SAFETY DATA SHEET



Cavex ColorChange

SECTION 1: Identification of the substance/mixture and of the company/undertaking**Product identifier****Product name** : Cavex ColorChange**Product type** : Alginate based powder, dustfree.**Relevant identified uses of the substance or mixture and uses advised against****Identified uses** : Dental impression material.**Details of the supplier of the safety data sheet****National contact**Cavex Holland
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

National advisory body/Poison Centre/Emergency telephone number**Telephone number** : +31 23 530 7700 (Office hours)**SECTION 2: Hazards identification****Classification of the substance or mixture****Product definition** : Powder.

See Section 16 for the full text of the R phrases or H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

Label elements**Europe****Supplemental label elements** : None.**Other hazards****Other hazards which do not result in classification** : None.**Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII** : Not applicable.**Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII** : Not applicable.**SECTION 3: Composition/information on ingredients****Substance/mixture** : Powder.

Product/ingredient name	Identifiers	%	Classification		Type
			67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	
Europe					
Magnesium oxide	CAS: 1309-48-4 EC: 215-171-9	1-5	Xi; R36/37/38	Not classified.	-
Tetra Sodium Pyrophosphate	CAS: 7722-88-5 EC: 231-767-1	0-3	Xi; R36/37/38	H315, H319, H335	[1]
Potassium Hexafluorotitanate	CAS: 16919-27-0 EC: 240-969-9	1-3	Xn; R20/21/22 Xi; R37, R41 See Section 16 for the full text of the R-phrases declared above.	H302, H317, H318 See Section 16 for the full text of the H statements declared above.	[1]

Type

1: Occupational exposure limits, if available, are listed in Section 8.

Date of issue/Date of revision : 16-10-2012. **Date of previous issue** : 30-8-2012. **Version** : 1.03 1/6

SECTION 4: First aid measures**Description of first aid measures**

- Eye contact** : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.
- Inhalation** : Not applicable.
- Skin contact** : Wash with soap and water.
- Ingestion** : No known significant effects or critical hazards. If you feel unwell, seek medical attention.
- Protection of first-aiders** : Not applicable.

Most important symptoms and effects, both acute and delayed**Potential acute health effects**

- Eye contact** : Irritating to eyes.
- Inhalation** : The product contains no relevant dust particles. The surface of the diatomaceous earth is coated with paraffines.
- Skin contact** : Non-irritating (EU).
- Ingestion** : No known significant effects or critical hazards.

Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Not considered to be toxic to humans.
- Specific treatments** : Not applicable.

SECTION 5: Firefighting measures**Extinguishing media**

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

Special hazards arising from the substance or mixture

- Hazards from the substance or mixture** : No known significant effects or critical hazards.
- Hazardous thermal decomposition products** : No known significant effects or critical hazards.

Advice for firefighters

- Special protective actions for fire-fighters** : None.
- Special protective equipment for fire-fighters** : Dust respirator.
- Additional information** : No additional remark.

SECTION 6: Accidental release measures**Personal precautions, protective equipment and emergency procedures**

- For non-emergency personnel** : Prevent formation of dust.
- For emergency responders** : Prevent formation of dust.
- Environmental precautions** : Avoid release to the environment.

Methods and materials for containment and cleaning up

- Small spill** : Use a shovel to transfer the material to a convenient waste disposal container.
- Large spill** : Avoid creating dusty conditions and prevent wind dispersal. Wear appropriate respiratory protection. Use a shovel to transfer the material to a convenient waste disposal container.

- Reference to other sections** : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

Precautions for safe handling

- Protective measures** : Prevent formation of dust.
- Advice on general occupational hygiene** : Store in a dry place.
- Conditions for safe storage, including any incompatibilities** : No specific storage is required.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
Europe	
Potassium Hexafluorotitanate	EU OEL (Europe). TWA: 1 mg/m ³ 8 hours.
Magnesium oxide	EU OEL (Europe). TWA: 1 mg/m ³ 8 hours.

Recommended monitoring procedures : None.

DNELs/DMELs : No DNELs/DMELs available.

PNECs : No PNECs available

Exposure controls

Appropriate engineering controls : Not applicable.

Individual protection measures

Hygiene measures : Not applicable.

Eye/face protection : Safety glasses.

Skin protection

Hand protection : Nitrile gloves.

Body protection : Lab coat.

Other skin protection : No known significant effects or critical hazards.

Respiratory protection : A respirator is not needed under normal and intended conditions of product use.

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

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance

Physical state : Solid. (Powder.)

Colour : Rose.

Odour : Peppermint-like.

pH : Not available.

Melting point/freezing point : No results available.

Initial boiling point and boiling range : No results available.

Flash point : No flammable ingredients present.

Relative density : Not determined.

Solubility in water : Partially soluble in cold water.

Auto-ignition temperature : No results available.

Decomposition temperature : No results available.

Viscosity : Testing not technically possible.

Oxidising properties : Not applicable.

Other information : No additional information.

SECTION 10: Stability and reactivity

Reactivity	: No additional information.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: None.
Conditions to avoid	: None.
Incompatible materials	: No specific data.
Hazardous decomposition products	: None.

SECTION 11: Toxicological information

Information on toxicological effects

<u>Acute toxicity</u>	: Very low toxicity to humans or animals.
<u>Irritation/Corrosion</u>	: Based on available data, the classification criteria are not met.
<u>Sensitisation</u>	: Based on available data, the classification criteria are not met.
<u>Mutagenicity</u>	: Based on available data, the classification criteria are not met.
<u>Carcinogenicity</u>	: Based on available data, the classification criteria are not met.
<u>Reproductive toxicity</u>	: Based on available data, the classification criteria are not met.
<u>Teratogenicity</u>	: Based on available data, the classification criteria are not met.

Potential acute health effects

Eye contact	: Irritating to eyes.
Inhalation	: The product contains no relevant dust particles. The surface of the diatomaceous earth is coated with paraffines.
Skin contact	: Non-irritating (EU).
Ingestion	: No known significant effects or critical hazards.

<u>Potential chronic health effects</u>	: No known significant effects or critical hazards.
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Other information	: No additional information.
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SECTION 12: Ecological information

Toxicity	: No results available.
Persistence and degradability	: No results available.
Bioaccumulative potential	: No results available.
Mobility in soil	: Not available.
Results of PBT and vPvB assessment	
PBT	: Not applicable.
vPvB	: Not applicable.
Other adverse effects	: No known significant effects or critical hazards.

SECTION 13: Disposal considerations

Waste treatment methods

<u>Product</u>	
Methods of disposal	: Use a shovel to transfer the material to a convenient waste disposal container.
Hazardous waste	: Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.
<u>Packaging</u>	
Methods of disposal	: Use a shovel to transfer the material to a convenient waste disposal container.
Special precautions	: Avoid breathing dust.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	Not controlled under European ADR.	Not controlled under ADN (Europe).	Not controlled under IMDG.	Not controlled under IATA.
Packing group	-	-	-	-
Environmental hazards				
Additional information	Non-dangerous substance	Non-dangerous substance	Non-dangerous substance	Non-dangerous substance

Special precautions for user

: No special measures are required.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

: Not available.

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

[EU Regulation \(EC\) No. 1907/2006 \(REACH\)](#)

[Annex XIV - List of substances subject to authorisation](#)

[Substances of very high concern](#)

None of the components are listed.

[National regulations](#)

Not applicable.

Chemical Safety Assessment

: No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms

: ATE = Acute Toxicity Estimate
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
 DMEL = Derived Minimal Effect Level
 DNEL = Derived No Effect Level
 EUH statement = CLP-specific Hazard statement
 PBT = Persistent, Bioaccumulative and Toxic
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number
 vPvB = Very Persistent and Very Bioaccumulative

[Procedure used to derive the classification according to Regulation \(EC\) No. 1272/2008 \[CLP/GHS\]](#)

Classification	Justification
Not classified.	

[Europe](#)

Full text of abbreviated H statements

: H302 - Harmful if swallowed.
 H315 - Causes skin irritation.
 H317 - May cause an allergic skin reaction.
 H318 - Causes serious eye damage.
 H319 - Causes serious eye irritation.
 H335 - May cause respiratory irritation.

Cavex ColorChange

SECTION 16: Other information

Full text of classifications [CLP/GHS]	: H302 - ACUTE TOXICITY: ORAL Category 4 H315 - SKIN CORROSION/IRRITATION Category 2 H317 - SKIN SENSITIZATION Category 1 H318 - IRRITANT Category 1 H319 - IRRITANT Category 2 H335 - STOT-SE = Specific Target Organ Toxicity - Single Exposure Category 3
Full text of abbreviated R phrases	: R20/21/22- Harmful by inhalation, in contact with skin and if swallowed. R36/37/38- Irritating to eyes, respiratory system and skin. R41- Risk of serious damage to eyes.
Full text of classifications [DSD/DPD]	: Xn - Harmful Xi - Irritant
Date of printing	: 16-10-2012.
Date of issue/ Date of revision	: 16-10-2012.
Date of previous issue	: 30-8-2012.
Version	: 1.03

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.10.2015

Revision: 08.10.2015

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

- **Product identifier**
- **Trade name:** Cavex ColorChange
- **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
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

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

· **Dangerous components:**

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	0.1-≤2.5%
EINECS: 215-171-9	substance with a Community workplace exposure limit	

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

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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.
- **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:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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 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

- **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:**

1309-48-4 magnesium oxide

WEL	Long-term value: 10* 4** mg/m ³ (as Mg) *inhalable dust **fume and respirable dust
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- **Additional information:** *The lists valid during the making were used as basis.*
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **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: | Whitish |
| Odour: | Pleasant |
| Odour threshold: | Not determined. |
| pH-value: | Not applicable. |
| · Change in condition | |
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |
| Flash point: | Not applicable. |
| Flammability (solid, gaseous): | Not determined. |
| · Ignition temperature: | |
| Decomposition temperature: | Not determined. |
| Self-igniting: | Product is not selfigniting. |
| Danger of explosion: | Product does not present an explosion hazard. |
| · Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| Vapour pressure: | Not applicable. |
| · Density: | |
| Relative density | Not determined. |
| Vapour density | Not applicable. |
| Evaporation rate | Not applicable. |

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Trade name: Cavex ColorChange

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· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	0.0 %
VOC (EC)	0.00 %
· Solids content:	100.0 %
· Other information	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)

- **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)

- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.

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Trade name: Cavex ColorChange

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- **Mobility in soil** No further relevant information available.
- **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** 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 | |
| · 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. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | 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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according to 1907/2006/EC, Article 31

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Trade name: Cavex ColorChange

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H335 May cause respiratory irritation.

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

· **Contact:** Mr. Nederstigt

· **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)

VOC: Volatile Organic Compounds (USA, EU)

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, Hazard Category 4

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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