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

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

- · Product identifier
- · Trade name: Cavex CA37 Normal Set
- · 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

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 GB 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.

- · 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 Talc (Mg3H2(SiO3)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%

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.

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.

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- · 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 (Mg3H2(SiO3)4)

WEL Long-term value: 1 mg/m³

1309-48-4 magnesium oxide

WEL Long-term value: 10* 4** mg/m3

(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.

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· 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:
Colour:
Pink
Odour:
Pleasant
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:
Upper:
Not determined.
Not determined.

Vapour pressure:
Not applicable.

Density:
Relative density
Vapour density
Vapour density
Evaporation rate
Not determined.
Not applicable.
Not applicable.

· Solubility in / Miscibility with

water: Insoluble.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not applicable. Kinematic: Not applicable.

· Solvent content:

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.

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11 Toxicological information

- · Information on toxicological effects
- · 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.
- · Additional toxicological information:
- · CMR effects (carcinogenity, 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: No further relevant information available.
- · 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.
- · 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

· 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.

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· 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.

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

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

* Data compared to the previous version altered.