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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 Individual Trays
- · UFI: DU20-G00M-K00V-HYYX
- 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: 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:

Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

- · 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: 12001-26-2 Mica substance with a Community workplace exposure limit 15-20% CAS: 13463-67-7 titanium dioxide substance with a Community workplace exposure limit 15-20%

EINECS: 236-675-5

· 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.
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

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· 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 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

- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

12001-26-2 Mica

OEL Long-term value: 3 mg/m³ respirable fraction

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: Wash hands before breaks and at the end of work.
- 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.

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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/face protection Not required.

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

Physical stateColour:SolidGrey

Odour: Recognisable
 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: 301 °C · Auto-ignition temperature: >300 °C

Decomposition temperature: Not determined.pH Not applicable.

· Viscosity:

· Kinematic viscosity Not applicable.

· Kinematic viscosity

Dynamic: Not applicable.

·Solubility

· water: Insoluble.

Partition coefficient n-octanol/water (log value)
 Vapour pressure:
 Not determined.
 Not applicable.

· Vapour pressure:

· Density and/or relative density

Density: Not determined.
 Relative density Not determined.
 Vapour density Not applicable.
 Particle characteristics See section 3.

· Other information

· Appearance:

· Form: Solid material

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

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· 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.
- · LD/LC50 values relevant for classification:

13463-67-7 titanium dioxide

Oral LD50 >20,000 mg/kg (rat)

Dermal LD50 >10,000 mg/kg (rabbit)

Inhalative LC50/4 h >6.82 mg/l (rat)

- · 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.
- · 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.

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- · 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

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 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.

- REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· 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.

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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.

- · 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative