

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

Printing date 02.04.2020

Revision: 02.04.2020

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

- **Product identifier**
- **Trade name:** *Cavex Non Gamma-2 predosed in capsules*
- **UFI:** *QW10-W0E8-700F-77K7*
- **Relevant identified uses of the substance or mixture and uses advised against**
Capsules, containing silver alloy and mercury (Hg).
I Spill: Alloy / Mercury 400/435 mg
II Spill: Alloy / Mercury 600/653 mg
III Spill: Alloy / Mercury 800/865 mg
- **Application of the substance / the mixture** *Dental filling material.*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Cavex Holland B.V.
Fustweg 5
2031 CJ Haarlem
T +31 23 530 7700 E-Mail : dental@cavex.nl
The Netherlands
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**



GHS06 skull and crossbones

Acute Tox. 2 H330 Fatal if inhaled.



GHS08 health hazard

Repr. 1B H360D May damage the unborn child.

STOT RE 1 H372 Causes damage to the central nervous system, the peripheral nervous system, the kidneys, the liver, the blood system, the cardiovascular system and the gingiva through prolonged or repeated exposure. Route of exposure: Inhalation.



GHS09 environment

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

- **Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**



GHS06



GHS08



GHS09

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 02.04.2020

Revision: 02.04.2020

Trade name: Cavex Non Gamma-2 predosed in capsules

(Contd. of page 1)

· **Signal word** Danger· **Hazard-determining components of labelling:**

mercury

· **Hazard statements**

H330 Fatal if inhaled.

H360D May damage the unborn child.

H372 Causes damage to the central nervous system, the peripheral nervous system, the kidneys, the liver, the blood system, the cardiovascular system and the gingiva through prolonged or repeated exposure.
Route of exposure: Inhalation.

H410 Very toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P284 [In case of inadequate ventilation] wear respiratory protection.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

Restricted to professional users.

· **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: 7439-97-6 EINECS: 231-106-7	mercury Acute Tox. 2, H330; Repr. 1B, H360D; STOT RE 1, H372; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	40-60%
CAS: 7440-50-8 EINECS: 231-159-6	copper substance with a Community workplace exposure limit	2.5-7.5%
CAS: 7440-66-6 EINECS: 231-175-3	zinc powder -zinc dust (stabilized) Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.025-<0.25%

· **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:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

Remove breathing equipment only after contaminated clothing have been completely removed.

In case of irregular breathing or respiratory arrest provide artificial respiration.

· **After inhalation:**

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 02.04.2020

Revision: 02.04.2020

Trade name: Cavex Non Gamma-2 predosed in capsules

(Contd. of page 2)

- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **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:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Mount respiratory protective device.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **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:** Keep container tightly sealed.
- **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.

(Contd. on page 4)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 02.04.2020

Revision: 02.04.2020

Trade name: Cavex Non Gamma-2 predosed in capsules

(Contd. of page 3)

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

7439-97-6 mercury

WEL	Long-term value: 0.02 mg/m ³ as Hg
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7440-50-8 copper

WEL	Short-term value: 2** mg/m ³ Long-term value: 0.2* 1** mg/m ³ *fume **dusts and mists (as Cu)
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· **Ingredients with biological limit values:**

7439-97-6 mercury

BMGV	20 µmol/mol creatinine Medium: urine Sampling time: random Parameter: mercury
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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:**

Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Protection of hands:**



Protective gloves

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:**



Tightly sealed goggles

GB

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 02.04.2020

Revision: 02.04.2020

Trade name: Cavex Non Gamma-2 predosed in capsules

(Contd. of page 4)

9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
· Form:	Fluid
· Colour:	Silver-coloured
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value: Not determined.	
· Change in condition	
· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	356 °C
· Flash point: Not applicable.	
· Flammability (solid, gas): Not applicable.	
· Decomposition temperature: Not determined.	
· Auto-ignition temperature: Product is not selfigniting.	
· Explosive properties: Product does not present an explosion hazard.	
· Explosion limits:	
· Lower:	Not determined.
· Upper:	Not determined.
· Vapour pressure: Not determined.	
· Density at 20 °C: 13.6 g/cm ³	
· Relative density Not determined.	
· Vapour density Not determined.	
· Evaporation rate Not determined.	
· Solubility in / Miscibility with water: Fully miscible.	
· Partition coefficient: n-octanol/water: Not determined.	
· Viscosity:	
· Dynamic:	Not determined.
· Kinematic:	Not determined.
· Solvent content:	
· VOC (EC)	0.00 %
· Solids content: 50.0 %	
· 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.

GB

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

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Revision: 02.04.2020

Trade name: Cavex Non Gamma-2 predosed in capsules

(Contd. of page 5)

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
Fatal if inhaled.
- **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**
May damage the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
Causes damage to the central nervous system, the peripheral nervous system, the kidneys, the liver, the blood system, the cardiovascular system and the gingiva through prolonged or repeated exposure. Route of exposure: Inhalation.
- **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.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms
- **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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

GB

(Contd. on page 7)

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








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Revision: 02.04.2020

Trade name: Cavex Non Gamma-2 predosed in capsules

(Contd. of page 6)

14 Transport information

· UN-Number · ADR, IMDG, IATA	UN3506
· UN proper shipping name · ADR · IMDG, IATA	3506 MERCURY CONTAINED IN MANUFACTURED ARTICLES solution, ENVIRONMENTALLY HAZARDOUS MERCURY CONTAINED IN MANUFACTURED ARTICLES solution
· Transport hazard class(es) · ADR	
  	
· Class · Label	8 Corrosive substances. 8+6.1
· IMDG	
 	
· Class · Label	8 Corrosive substances. 8/6.1
· IATA	
 	
· Class · Label	8 Corrosive substances. 8 (6.1)
· ADR, IMDG, IATA	not regulated
· Environmental hazards:	Product contains environmentally hazardous substances: mercury
· Special marking (ADR):	Symbol (fish and tree)
· Special precautions for user	Not applicable.
· Hazard identification number (Kemler code):	86
· EMS Number:	F-A,S-B
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· Segregation Code	SG24 Stow "away from" SGG17-azides
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	5 kg Code: E0 Not permitted as Excepted Quantity
· Transport category	3
· Tunnel restriction code	E

(Contd. on page 8)

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

Printing date 02.04.2020

Revision: 02.04.2020

Trade name: Cavex Non Gamma-2 predosed in capsules

(Contd. of page 7)

· IMDG	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E0 Not permitted as Excepted Quantity
· UN "Model Regulation":	UN 3506 MERCURY CONTAINED IN MANUFACTURED ARTICLES SOLUTION, 8 (6.1), ENVIRONMENTALLY HAZARDOUS

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.
- **Seveso category**
H2 ACUTE TOXIC
E1 Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 18a, 30

- **Regulation (EU) No 649/2012**

7439-97-6 mercury

Annex I Part 1
Annex I Part 3
Annex V Part 2

- **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**

H330 Fatal if inhaled.

H360D May damage the unborn child.

H372 Causes damage to the central nervous system, the peripheral nervous system, the kidneys, the liver, the blood system, the cardiovascular system and the gingiva through prolonged or repeated exposure.
Route of exposure: Inhalation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- **Department issuing SDS:** Product safety department

- **Contact:** .

- **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 2: Acute toxicity - inhalation - Category 2

Repr. 1B: Reproductive toxicity - Category 1B

STOT RE 1: Specific target organ toxicity (repeated exposure) - Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1