

# Safety data sheet

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 20150601

Version: 201607\_8\_1

replaces version dated:

20130308

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## Section 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Trade name: CFT Control Antigens

Product no.: 21xx, 22xx, 23xx, 92xx

### 1.2 Relevant identified uses of the substance or mixture and discouraged uses

*Identified use:* In vitro diagnostic agent or component of an in vitro diagnostic agent

*Discouraged uses:* No other relevant data available.

### 1.3 Details of the supplier of the safety data sheet

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19

97076 Würzburg

Germany

Tel. 0049 (0) 931 – 30 45 0

Fax 0049 (0) 931 – 30 45 100

Email [info@virion-serion.de](mailto:info@virion-serion.de)

### 1.4 Emergency telephone number

Manufacturer: 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 a.m. to 4:00 p.m.)

## Section 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008**

Acute dermal toxicity, category 4, H312

Water hazard: Chronic, category 3, H412

### 2.2 Label elements

Hazard pictogram(s)



Signal word: **Caution**

H statements:

H312: Harmful in contact with skin.

H412: Harmful to aquatic organisms with long-lasting effects.

P statements:

P273: Avoid release to the environment.

P280: Wear protective gloves/ protective clothing.

P302 + P352: IF ON SKIN: Wash with plenty of water and soap.

P312: Call a POISON CENTER or doctor if you feel unwell.

P501: Dispose of contents/container to an approved disposal company.

### 2.3 Other hazards

This product contains chemically and/or physically inactivated biological agents and should be considered potentially infectious.

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### Section 3: Composition/information on ingredients

#### 3.1 Substance

Not applicable

#### 3.2 Mixture

Thiomersal

EC No.: 200-210-4; Index number: 080-004-00-7; CAS no. 45-64-8

Percentage: <0.3%

#### Classification according to Regulation (EC) No. 1272/2008:

Acute tox. 2; H330 Fatal if swallowed.

Acute tox. 1; H310 Fatal in contact with skin.

Acute tox. 2; H330 Fatal if swallowed.

STOT RE 2; H373 May cause damage to organs through prolonged or repeated exposure.

Aquatic Acute 1; H400 Very toxic to aquatic organisms.

Aquatic Chronic 1; H410 Very toxic to aquatic organisms with long-lasting effects.

### Section 4: First aid measures

#### 4.1 Description of first aid measures

General instructions: Administer artificial respiration for irregular respiration or respiratory arrest.

Consult a doctor immediately.

Following inhalation: Fresh air or administer oxygen. Consult a doctor.

Following skin contact: Wash off with plenty of water. Remove contaminated clothing immediately. See a doctor if there are any symptoms.  
Treat affected areas with skin disinfectant.

Following eye contact: Flush eyes with plenty of water and intermittently lift the upper and lower eyelids. Check for contact lenses and remove if present.  
Consult doctor.

Following ingestion: Rinse out mouth and drink plenty of water (max. 2 glasses). Do not induce vomiting. Consult a doctor if feeling unwell.

#### 4.2 Most important symptoms and effects, both acute and delayed

No information available.

#### 4.3 Indication of any immediate medical attention and special treatment needed

No information available.

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### **Section 5: Firefighting measures**

#### **5.1 Extinguishing media**

Suitable extinguishing media

Use extinguishing measures appropriate to the environment.

Unsuitable extinguishing media

There are no restrictions for the extinguishing media used for this substance/mixture.

#### **5.2 Special hazards arising from the substance or mixture**

Non-flammable. Heating or fire may release hazardous gases. Sulphur oxides (SO<sub>x</sub>) may be released in case of fire. A fire in the nearby surroundings may generate hazardous vapours.

#### **5.3 Advice for firefighters**

Special protective equipment for firefighters

Self-contained breathing apparatus required when in the hazard area. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing. Fire residues and contaminated extinguishing water must be disposed of in accordance with legal requirements.

### **Section 6: Accidental release measures**

#### **6.1 Personal precautions, protective equipment and emergency procedures**

##### **6.1.1 Information for non-emergency personnel**

Do not breathe vapour/aerosol. Avoid contact with substance. Ensure adequate ventilation. Evacuate the danger zone, follow the emergency plan, consult specialists.

##### **6.1.2 Information for emergency responders**

Protective equipment: see section 8.

#### **6.2 Environmental precautions**

Do not empty into drains.

#### **6.3 Methods and materials for containment and cleaning up**

Remove containers from the discharge area. Avoid discharging into the sewer system, bodies of water, basements or closed areas. Collect the material and put in appropriately labelled waste containers. Dispose of through an accredited waste disposal company. Clean.

#### **6.4 Reference to other sections**

Instructions for disposal, see section 13.

### **Section 7: Handling and storage**

#### **7.1 Precautions for safe handling**

##### **7.1.1 Advice on safe handling**

Avoid exposure. Follow the instructions on the label. Ensure good ventilation and extraction. Open containers carefully.

##### **7.1.2 Hygiene measures**

Change contaminated clothing immediately. Apply preventive skin protection. Wash hands after working with substance.

#### **7.2 Conditions for safe storage, including any incompatibilities**

##### **Requirements for storage areas and vessels:**

Keep only in the original container. Prevent leakage into soil.

#### **7.3 Specific end uses**

Apart from the intended use as per Section 1.2, no other specific end uses are stipulated.

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### Section 8: Exposure controls/ Personal protective equipment

#### 8.1 Control parameters

Constituents with workplace-related limit values that must be monitored

Thiomersal (CAS no. 54-64-8)	
MWC	Section IV

#### 8.2 Exposure controls

##### 8.2.1 Appropriate engineering controls

Ensure good general ventilation at the workplace.

##### 8.2.2 Personal protection measures

When using do not eat, drink or smoke. Wash hands before breaks and after work. Avoid contact with clothing. Remove contaminated clothing and clean thoroughly. Change work clothing before breaks if necessary.

##### 8.2.2.1 Eye/face protection

Adequate eye protection should be worn.

Use framed glasses with a side shield.

##### 8.2.2.2 Skin protection

###### Hand protection

The glove material must be impermeable and resistant to the product/substance/preparation. Select glove material with reference to penetration times, permeation rates and degradation.

###### Glove material

The selection of a suitable glove depends not only on the material but also on other quality features and varies from manufacturer to manufacturer.

###### Penetration time of the glove material

The exact penetration time must be specified by the glove manufacturer and must be observed.

###### Gloves of the following materials are suitable for continuous contact:

Nitrile rubber

Recommended thickness:  $\geq 0.11$  mm

Value for permeation: Level  $\geq 480$  min

###### Gloves of the following materials are suitable for spray protection:

Nitrile rubber

Recommended thickness:  $\geq 0.11$  mm

Value for permeation: Level  $\geq 480$  min

###### Other safety precautions

Select suitable protection equipment for the workplace depending on the concentration and volume of the hazardous substance.

##### 8.2.2.3 Respiratory protection

Respiratory protection is required if dust is generated.

Respiratory filter device for short-term or low volumes; self-contained breathing apparatus for intensive or extended exposure.

Respiratory protection is required if dust is generated.

Special gas filter Hg-P38.

#### 8.2.3 Environmental exposure controls

Do not empty into drains. Discharge into the environment must be avoided.

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### Section 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Appearance	Physical state: Solid pellet Colour: Yellowish white or light violet
Odour	No data available
Odour threshold	No data available
pH	No data available
Melting point	No data available
Boiling point	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Lower explosion limit	No data available
Upper explosion limit	No data available
Vapour pressure	No data available
Vapour density	No data available
Relative density	No data available
Water solubility at 20 °C	Soluble
Partition coefficient: n-octanol/water	No data available
Auto-ignition temperature	Not applicable
Decomposition temperature	No data available
Viscosity, dynamic	No information available
Explosive properties	No information available
Oxidising properties	No data available

#### 9.2 Other information

No other relevant information available.

### Section 10: Stability and reactivity

#### 10.1 Reactivity

No information available.

#### 10.2 Chemical stability

The product is chemically stable under the specified storage conditions.

#### 10.3 Possibility of hazardous reactions

No information available.

#### 10.4 Conditions to avoid

No information available.

#### 10.5 Incompatible materials

No information available.

#### 10.6 Hazardous decomposition products

In the event of fire, sulphur oxides (SO<sub>x</sub>) may be generated.

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### **Section 11: Toxicological information**

#### **11.1 Information on toxicological effects**

Mixture

##### **Acute oral toxicity**

No information available.

##### **Acute inhalative toxicity**

No information available.

##### **Acute dermal toxicity**

No information available.

##### **Skin irritation**

No information available.

##### **Eye irritation**

No information available.

##### **Sensitisation**

No information available.

##### **Germ cell mutagenicity**

No information available.

##### **Carcinogenicity**

No information available.

##### **Reproductive toxicity**

No information available.

##### **Teratogenicity**

No information available.

##### **Specific target organ toxicity - single exposure**

No information available.

##### **Specific target organ toxicity - repeated exposure**

No information available.

##### **Aspiration hazard**

No information available.

#### **11.2 Other information**

Quantitative data on the toxicity of this product are not available.

This product contains chemically inactivated biological agents and should be considered potentially infectious.

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### Section 12: Ecological information

Mixture

#### 12.1 Toxicity

No information available.

#### 12.2 Persistence and degradability

No information available.

#### 12.3 Bioaccumulation potential

No information available.

#### 12.4 Mobility in soil

No information available.

#### 12.5 Results of PBT and vPvB assessment

There is no PBT/vPvB assessment available because no chemical safety assessment is required/was conducted.

#### 12.6 Other adverse effects

No information available.

#### Additional ecological information

Discharge into the environment must be avoided.

### Section 13: Disposal considerations

#### Waste treatment methods

Dispose of leftover product in accordance with Directive 2008/98/EC on waste and national and regional regulations. Do not mix with other waste. Handle uncleaned containers like the product itself.

### Section 14: Transport information

**14.1 UN number** not classified as dangerous goods as per ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).

**14.2 Proper UN shipping name** not applicable

**14.3 Transport hazard class** not applicable

**14.4 Packing group** not applicable

**14.5 Environmental hazard** none

**14.6 Special precautions for user** none

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

Not relevant

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### **Section 15: Regulatory information**

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

EU regulations none known

National regulations none known

#### **15.2 Chemical safety assessment**

A chemical safety assessment has not been conducted for this product.

### **Section 16: Other information**

#### **Full text of hazard warnings in section 3.2:**

H statements:

H312: Harmful in contact with skin.

H412: Harmful to aquatic organisms with long-lasting effects.

The information describes the product with reference to the applicable safety precautions. It is not an assurance of the properties of the product.