

**Safety data sheet**  
according to Regulation (EC) No 1907/2006,  
Article 31 including amending Regulation  
EU/2020/878

Printing date 01.07.2024

Version number 1

Revision: 01.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Controllo negativo - Febrile MK
- **Article number:** CSI087388
- **1.2 Relevant identified uses of the substance or mixture and uses  
advised against**  
Relevant Identified Uses: For laboratory use only  
Uses advised against: Uses other than those recommended
- **Application of the substance / the mixture** Diagnostic reagent
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Sclavo Diagnostics International  
Via Po 26-28, Loc. Pian dei Mori  
CAP: 53018 - SOVICILLE - (SI)  
ITALY
- **Further information obtainable from:** Product safety department.
- **1.4 Emergency telephone number:** +39 0577 390 444 / 445

**2 Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**3 Composition/information on ingredients**

- **3.2 Mixtures**
- **Description:**  
Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void

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

#### 4 First aid measures

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed**  
 No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
 No further relevant information available.

#### 5 Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
 Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**  
 No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

#### 6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
 Not required.
- **6.2 Environmental precautions:**  
 Dilute with plenty of water.  
 Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
 Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:**  
 No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
 No special requirements.

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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:**  
The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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.
- **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** Goggles recommended during refilling

## 9 Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid
- **Colour:** Colourless
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** 0 °C
- **Boiling point or initial boiling point and boiling range** 100 °C (7732-18-5 water, distilled, conductivity or of similar purity)
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.

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· <b>Flash point:</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>pH</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>Dynamic at 20 °C:</b>	0.952 mPas
· <b>Solubility</b>	
· <b>water:</b>	Fully miscible.
· <b>Partition coefficient n-octanol/ water (log value)</b>	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
· <b>Density and/or relative density</b>	
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>9.2 Other information</b>	
· <b>Appearance:</b>	
· <b>Form:</b>	Fluid
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Solvent content:</b>	
· <b>Water:</b>	95.8 %
· <b>VOC (EC)</b>	0.00 %
· <b>Solids content:</b>	3.9 %
· <b>Molecular weight</b>	18.02 g/mol
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void

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· **Desensitised explosives**                      Void

## 10 Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**  
No dangerous decomposition products known.

## 11 Toxicological information

- **11.1 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:**

### ATE (Acute Toxicity Estimates)

Oral	LD50	15,235 mg/kg
Dermal	LD50	11,285 mg/kg

- **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.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties**  
The product contains substances, which affect the thyroid system and other hormonal systems.

None of the ingredients is listed.

## 12 Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.

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- **12.2 Persistence and degradability**  
No further relevant information available.
- **12.3 Bioaccumulative potential**  
No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 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

- **13.1 Waste treatment methods**
- **Recommendation**  
Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:**  
Disposal must be made according to official regulations.
- **Recommended cleansing agents:**  
Water, if necessary together with cleansing agents.

### 14 Transport information

- |   |                 |
|---|-----------------|
| • <b>14.1 UN number or ID number</b>                                  |                 |
| • <b>ADR, IMDG, IATA</b>  | not regulated   |
| • <b>14.2 UN proper shipping name</b>                                 |                 |
| • <b>ADR, IMDG, IATA</b>  | not regulated   |
| • <b>14.3 Transport hazard class(es)</b>                              |                 |
| • <b>ADR, ADN, IMDG, IATA</b>   |                 |
| • <b>Class</b>  | not regulated   |
| • <b>14.4 Packing group</b>   |                 |
| • <b>ADR, IMDG, IATA</b>  | not regulated   |
| • <b>14.5 Environmental hazards:</b>                                  | Not applicable. |
| • <b>14.6 Special precautions for user</b>                            | Not applicable. |
| • <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| • <b>UN "Model Regulation":</b>                                       | not regulated   |

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## 15 Regulatory information

- **15.1 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.
- **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.
- **15.2 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.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

- **Department issuing SDS:** Product safety department.
- **Contact:** -
- **Date of previous version:** 25.06.2024
- **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)  
 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
- **\* Data compared to the previous version altered.**