



08.07.2024

Kit Components

Product code	Description
CSI087309	FEBRILE ANTIGEN KIT CSI087309

Components:

150302	Typhi O - Febrile Antigen kit
150303	Typhi H - Febrile Antigen Kit
150305	P. Typhi B O - Febrile Antigen Kit
150306	P. Typhi B H - Febrile Antigen Kit
192196	P. Typhi A O - Febrile Antigen
192197	P. Typhi A H - Febrile Antigen Kit
150301	Brucella - Febrile Antigen Kit
192150	Controllo negativo - Febrile
192149	Controllo positivo - Febrile

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Typhi O - Febrile Antigen kit
- **Article number:** 150302
- **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:**

CAS: 56-81-5	glycerol	>2.5-≤10%
EINECS: 200-289-5	substance with a Community workplace exposure limit	

(Contd. on page 2)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi O - Febrile Antigen kit

(Contd. of page 1)

- **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.

(Contd. on page 3)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi O - Febrile Antigen kit

(Contd. of page 2)

- **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:**

56-81-5 glycerol

OEL Long-term value: 10 mg/m³

· **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:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **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.

(Contd. on page 4)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi O - Febrile Antigen kit

(Contd. of page 3)

• Upper:	Not determined.
• Flash point:	199 °C (56-81-5 glycerol)
• Auto-ignition temperature:	400 °C (56-81-5 glycerol)
• Decomposition temperature:	Not determined.
• pH	Not determined.
• Viscosity:	
• Kinematic viscosity	Not determined.
• Dynamic:	Not determined.
• Solubility	
• water:	Fully miscible.
• Partition coefficient n-octanol/ water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
• Density and/or relative density	
• Density:	Not determined.
• Relative density	Not determined.
• Vapour density	Not determined.
• 9.2 Other information	
• Appearance:	
• Form:	Fluid
• 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:	
• Organic solvents:	8.3 %
• Water:	90.7 %
• VOC (EC)	0.00 %
• Solids content:	0.8 %
• Change in condition	
• Evaporation rate	Not determined.
• 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
• 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

(Contd. on page 5)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi O - Febrile Antigen kit

(Contd. of page 4)

- | | |
|----------------------------------|------|
| • Corrosive to metals | Void |
| • 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:**

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

- **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.

(Contd. on page 6)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi O - Febrile Antigen kit

(Contd. of page 5)

- **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

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

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(Contd. on page 7)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi O - Febrile Antigen kit

(Contd. of page 6)

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:** -
- **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

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Typhi H - Febrile Antigen Kit
- **Article number:** 150303
- **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:**

CAS: 56-81-5	glycerol	0.25-5%
EINECS: 200-289-5	substance with a Community workplace exposure limit	

(Contd. on page 2)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi H - Febrile Antigen Kit

(Contd. of page 1)

· **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.

(Contd. on page 3)

Safety data sheet

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi H - Febrile Antigen Kit

(Contd. of page 2)

- **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:**

56-81-5 glycerol

OEL Long-term value: 10 mg/m³

· **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:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **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.

(Contd. on page 4)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi H - Febrile Antigen Kit

(Contd. of page 3)

• Upper:	Not determined.
• Flash point:	199 °C (56-81-5 glycerol)
• Auto-ignition temperature:	400 °C (56-81-5 glycerol)
• Decomposition temperature:	Not determined.
• pH	Not determined.
• Viscosity:	
• Kinematic viscosity	Not determined.
• Dynamic:	Not determined.
• Solubility	
• water:	Fully miscible.
• Partition coefficient n-octanol/ water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
• Density and/or relative density	
• Density:	Not determined.
• Relative density	Not determined.
• Vapour density	Not determined.
• 9.2 Other information	
• Appearance:	
• Form:	Fluid
• 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:	
• Organic solvents:	5.0 %
• Water:	93.9 %
• VOC (EC)	0.00 %
• Solids content:	0.9 %
• Change in condition	
• Evaporation rate	Not determined.
• 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
• 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

(Contd. on page 5)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi H - Febrile Antigen Kit

(Contd. of page 4)

- | | |
|----------------------------------|------|
| • Corrosive to metals | Void |
| • 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:**

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

- **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.

(Contd. on page 6)

Safety data sheet
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Trade name: Typhi H - Febrile Antigen Kit

(Contd. of page 5)

- **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

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

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(Contd. on page 7)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Typhi H - Febrile Antigen Kit

(Contd. of page 6)

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:** -
- **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

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** P. Typhi B O - Febrile Antigen Kit
- **Article number:** 150305
- **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:**

CAS: 56-81-5	glycerol	0.25-5%
EINECS: 200-289-5	substance with a Community workplace exposure limit	

(Contd. on page 2)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi B O - Febrile Antigen Kit

(Contd. of page 1)

• **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.

(Contd. on page 3)

Safety data sheet

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi B O - Febrile Antigen Kit

(Contd. of page 2)

- **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:**

56-81-5 glycerol

OEL Long-term value: 10 mg/m³

· **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.

(Contd. on page 4)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **P. Typhi B O - Febrile Antigen Kit**

(Contd. of page 3)

• Upper:	Not determined.
• Flash point:	Not applicable.
• Decomposition temperature:	Not determined.
• pH	Not determined.
• Viscosity:	
• Kinematic viscosity	Not determined.
• Dynamic at 20 °C:	0.952 mPas
• Solubility	
• water:	Fully miscible.
• Partition coefficient n-octanol/ water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
• Density and/or relative density	
• Density at 20 °C:	1 g/cm ³
• Relative density	Not determined.
• Vapour density	Not determined.

• 9.2 Other information	
• Appearance:	
• Form:	Fluid
• 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:	
• Organic solvents:	3.0 %
• Water:	95.9 %
• VOC (EC)	0.00 %
• Solids content:	0.9 %
• Molecular weight	18.02 g/mol
• Change in condition	
• Evaporation rate	Not determined.

• 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
• 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

(Contd. on page 5)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi B O - Febrile Antigen Kit

(Contd. of page 4)

- | | |
|----------------------------------|------|
| • Corrosive to metals | Void |
| • 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:**

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

- **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.

(Contd. on page 6)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi B O - Febrile Antigen Kit

(Contd. of page 5)

- **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

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

IE

(Contd. on page 7)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **P. Typhi B O - Febrile Antigen Kit**

(Contd. of page 6)

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:** -
- **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

Safety data sheet
according to Regulation (EC) No 1907/2006,
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EU/2020/878

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** P. Typhi B H - Febrile Antigen Kit
- **Article number:** 150306
- **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:**

CAS: 56-81-5	glycerol	>10-≤25%
EINECS: 200-289-5	substance with a Community workplace exposure limit	

(Contd. on page 2)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi B H - Febrile Antigen Kit

(Contd. of page 1)

- **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.

(Contd. on page 3)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi B H - Febrile Antigen Kit

(Contd. of page 2)

- **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:**

56-81-5 glycerol

OEL Long-term value: 10 mg/m³

· **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:**

According to product specification

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

Undetermined.

- **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.

(Contd. on page 4)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **P. Typhi B H - Febrile Antigen Kit**

(Contd. of page 3)

• Upper:	Not determined.
• Flash point:	199 °C (56-81-5 glycerol)
• Auto-ignition temperature:	400 °C (56-81-5 glycerol)
• Decomposition temperature:	Not determined.
• pH	Not determined.
• Viscosity:	
• Kinematic viscosity	Not determined.
• Dynamic:	Not determined.
• Solubility	
• water:	Fully miscible.
• Partition coefficient n-octanol/ water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
• Vapour pressure at 50 °C:	~0 hPa
• Density and/or relative density	
• Density:	Not determined.
• Relative density	Not determined.
• Vapour density	Not determined.
• 9.2 Other information	
• Appearance:	
• Form:	Fluid
• 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:	
• Organic solvents:	20.0 %
• Water:	79.1 %
• VOC (EC)	0.00 %
• Solids content:	0.7 %
• Change in condition	
• Evaporation rate	Not determined.
• 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
• 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

(Contd. on page 5)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi B H - Febrile Antigen Kit

(Contd. of page 4)

- | | |
|----------------------------------|------|
| • Organic peroxides | Void |
| • Corrosive to metals | Void |
| • 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:**

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

- **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.

IE

(Contd. on page 6)

Safety data sheet
according to Regulation (EC) No 1907/2006,
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EU/2020/878

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi B H - Febrile Antigen Kit

(Contd. of page 5)

12 Ecological information

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

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

(Contd. on page 7)

IE

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi B H - Febrile Antigen Kit

(Contd. of page 6)

- **UN "Model Regulation":** not regulated

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 Sheets 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:** -
- **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

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** P. Typhi A O - Febrile Antigen
- **Article number:** 192196
- **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:**

CAS: 56-81-5	glycerol	>2.5-≤10%
EINECS: 200-289-5	substance with a Community workplace exposure limit	

(Contd. on page 2)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A O - Febrile Antigen

(Contd. of page 1)

- **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.

(Contd. on page 3)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A O - Febrile Antigen

(Contd. of page 2)

- **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:**

56-81-5 glycerol

OEL Long-term value: 10 mg/m³

- **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:**

According to product specification

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

Undetermined.

- **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.

(Contd. on page 4)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A O - Febrile Antigen

(Contd. of page 3)

• Upper:	Not determined.
• Flash point:	199 °C (56-81-5 glycerol)
• Auto-ignition temperature:	400 °C (56-81-5 glycerol)
• Decomposition temperature:	Not determined.
• pH	Not determined.
• Viscosity:	
• Kinematic viscosity	Not determined.
• Dynamic:	Not determined.
• Solubility	
• water:	Fully miscible.
• Partition coefficient n-octanol/ water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
• Density and/or relative density	
• Density:	Not determined.
• Relative density	Not determined.
• Vapour density	Not determined.
• 9.2 Other information	
• Appearance:	
• Form:	Fluid
• 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:	
• Organic solvents:	8.0 %
• Water:	91.0 %
• VOC (EC)	0.00 %
• Solids content:	0.8 %
• Change in condition	
• Evaporation rate	Not determined.
• 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
• 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

(Contd. on page 5)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A O - Febrile Antigen

(Contd. of page 4)

- | | |
|----------------------------------|------|
| • Corrosive to metals | Void |
| • 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:**

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

- **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.

(Contd. on page 6)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A O - Febrile Antigen

(Contd. of page 5)

- **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

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

IE

(Contd. on page 7)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **P. Typhi A O - Febrile Antigen**

(Contd. of page 6)

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:** -
- **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

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** P. Typhi A H - Febrile Antigen Kit
- **Article number:** 192197
- **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:**

CAS: 56-81-5	glycerol	>10-≤25%
EINECS: 200-289-5	substance with a Community workplace exposure limit	

(Contd. on page 2)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A H - Febrile Antigen Kit

(Contd. of page 1)

• **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.

(Contd. on page 3)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A H - Febrile Antigen Kit

(Contd. of page 2)

- **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:**

56-81-5 glycerol

OEL Long-term value: 10 mg/m³

· **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:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **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.

(Contd. on page 4)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A H - Febrile Antigen Kit

(Contd. of page 3)

• Upper:	Not determined.
• Flash point:	199 °C (56-81-5 glycerol)
• Auto-ignition temperature:	400 °C (56-81-5 glycerol)
• Decomposition temperature:	Not determined.
• pH	Not determined.
• Viscosity:	
• Kinematic viscosity	Not determined.
• Dynamic:	Not determined.
• Solubility	
• water:	Fully miscible.
• Partition coefficient n-octanol/ water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
• Vapour pressure at 50 °C:	~0 hPa
• Density and/or relative density	
• Density:	Not determined.
• Relative density	Not determined.
• Vapour density	Not determined.
• 9.2 Other information	
• Appearance:	
• Form:	Fluid
• 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:	
• Organic solvents:	20.0 %
• Water:	79.1 %
• VOC (EC)	0.00 %
• Solids content:	0.7 %
• Change in condition	
• Evaporation rate	Not determined.
• 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
• 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

(Contd. on page 5)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A H - Febrile Antigen Kit

(Contd. of page 4)

- | | |
|----------------------------------|------|
| • Organic peroxides | Void |
| • Corrosive to metals | Void |
| • 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:**

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

- **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.

IE

(Contd. on page 6)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A H - Febrile Antigen Kit

(Contd. of page 5)

12 Ecological information

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

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

(Contd. on page 7)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: P. Typhi A H - Febrile Antigen Kit

(Contd. of page 6)

- **UN "Model Regulation":** not regulated

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 Sheets 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:** -
- **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

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Brucella - Febrile Antigen Kit
- **Article number:** 150301
- **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:**

CAS: 56-81-5	glycerol	>2.5-≤10%
EINECS: 200-289-5	substance with a Community workplace exposure limit	

(Contd. on page 2)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Brucella - Febrile Antigen Kit

(Contd. of page 1)

- **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.

(Contd. on page 3)

Safety data sheet

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Brucella - Febrile Antigen Kit

(Contd. of page 2)

- **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:**

56-81-5 glycerol

OEL Long-term value: 10 mg/m³

· **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:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **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.

(Contd. on page 4)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **Brucella - Febrile Antigen Kit**

(Contd. of page 3)

• Upper:	Not determined.
• Flash point:	199 °C (56-81-5 glycerol)
• Auto-ignition temperature:	400 °C (56-81-5 glycerol)
• Decomposition temperature:	Not determined.
• pH	Not determined.
• Viscosity:	
• Kinematic viscosity	Not determined.
• Dynamic:	Not determined.
• Solubility	
• water:	Fully miscible.
• Partition coefficient n-octanol/ water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
• Density and/or relative density	
• Density:	Not determined.
• Relative density	Not determined.
• Vapour density	Not determined.
• 9.2 Other information	
• Appearance:	
• Form:	Fluid
• 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:	
• Organic solvents:	9.7 %
• Water:	100.0 %
• VOC (EC)	0.00 %
• Solids content:	1.0 %
• Change in condition	
• Evaporation rate	Not determined.
• 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
• 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

(Contd. on page 5)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **Brucella - Febrile Antigen Kit**

(Contd. of page 4)

- | | |
|----------------------------------|------|
| • Corrosive to metals | Void |
| • 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:**

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

- **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.

(Contd. on page 6)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Brucella - Febrile Antigen Kit

(Contd. of page 5)

- **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

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

IE

(Contd. on page 7)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **Brucella - Febrile Antigen Kit**

(Contd. of page 6)

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:** -
- **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

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Controllo negativo - Febrile
- **Article number:** 192150
- **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

(Contd. on page 2)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Controllo negativo - Febrile

(Contd. of page 1)

· **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.

(Contd. on page 3)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Controllo negativo - Febrile

(Contd. of page 2)

- **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.

(Contd. on page 4)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **Controllo negativo - Febrile**

(Contd. of page 3)

· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic at 20 °C:	0.952 mPas
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/ water (log value)	Not determined.
· Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· 9.2 Other information	
· Appearance:	
· Form:	Fluid
· 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:	
· Water:	95.8 %
· VOC (EC)	0.00 %
· Solids content:	3.9 %
· Molecular weight	18.02 g/mol
· Change in condition	
· Evaporation rate	Not determined.
· 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
· 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

(Contd. on page 5)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Controllo negativo - Febrile

(Contd. of page 4)

· **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.

(Contd. on page 6)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Controllo negativo - Febrile

(Contd. of page 5)

- **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

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

IE

(Contd. on page 7)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **Controllo negativo - Febbile**

(Contd. of page 6)

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.**

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Controllo positivo - Febrile
- **Article number:** 192149
- **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

(Contd. on page 2)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Controllo positivo - Febrile

(Contd. of page 1)

- **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.

(Contd. on page 3)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Controllo positivo - Febrile

(Contd. of page 2)

- **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.

(Contd. on page 4)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: **Controllo positivo - Febrile**

(Contd. of page 3)

· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic at 20 °C:	0.952 mPas
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/ water (log value)	Not determined.
· Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· 9.2 Other information	
· Appearance:	
· Form:	Fluid
· 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:	
· Water:	95.8 %
· VOC (EC)	0.00 %
· Solids content:	3.9 %
· Molecular weight	18.02 g/mol
· Change in condition	
· Evaporation rate	Not determined.
· 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
· 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

(Contd. on page 5)

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

Printing date 08.07.2024

Version number 1

Revision: 08.07.2024

Trade name: Controllo positivo - Febrile

(Contd. of page 4)

· **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.

(Contd. on page 6)

Safety data sheet
according to Regulation (EC) No 1907/2006,
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EU/2020/878

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Revision: 08.07.2024

Trade name: Controllo positivo - Febrile

(Contd. of page 5)

- **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

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

IE

(Contd. on page 7)

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(Contd. of page 6)

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.

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- **Date of previous version:** 25.06.2024
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 VOC: Volatile Organic Compounds (USA, EU)
 LC50: Lethal concentration, 50 percent
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 PBT: Persistent, Bioaccumulative and Toxic
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- *** Data compared to the previous version altered.**