



09.04.2024

Kit Components

Product code	Description
CSI050016	Siero agglutinante shigella sonnei polivalente / Polyvalent shigella sonnei agglutinantig sera CSI050016

Components:

250012	Siero Agglutinante
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Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31

Printing date 09.04.2024

Version number 1

Revision: 13.12.2023

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Siero Agglutinante
- **Article number:** 250012
- **UFI:** Q7P0-X0Y1-0007-1MVN
- **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
- **Additional information:**
For the wording of the listed hazard phrases refer to section 16.

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

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Version number 1

Revision: 13.12.2023

Trade name: Siero Agglutinante

(Contd. of page 1)

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.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.

(Contd. on page 3)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 09.04.2024

Version number 1

Revision: 13.12.2023

Trade name: Siero Agglutinante

(Contd. of page 2)

- **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:** Clear
- **Odour:** Odourless
- **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.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH** Not determined.

(Contd. on page 4)

Safety data sheet

according to Regulation (EC) No 1907/2006,
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Printing date 09.04.2024

Version number 1

Revision: 13.12.2023

Trade name: Siero Agglutinante

(Contd. of page 3)

- | | |
|---|---|
| • 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. |
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- | | |
|--|--|
| • 9.2 Other information | |
| • Appearance: | |
| • Form: | Solid in various forms |
| • 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: | 77.5 % |
| • VOC (EC) | 0.00 % |
| • Solids content: | 0.0 % |
| • 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 |
| • Corrosive to metals | Void |
| • Desensitised explosives | Void |

10 Stability and reactivity

- **10.1 Reactivity** No further relevant information available.

(Contd. on page 5)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 09.04.2024

Version number 1

Revision: 13.12.2023

Trade name: Siero Agglutinante

(Contd. of page 4)

- **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.
- **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.
- **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.

(Contd. on page 6)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 09.04.2024

Version number 1

Revision: 13.12.2023

Trade name: Siero Agglutinante

(Contd. of page 5)

- **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 |

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.

(Contd. on page 7)

Safety data sheet
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(Contd. of page 6)

· **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.

· **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)
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative