



19.03.2025

Kit Components

| Product code | Description |
|--------------|-------------|
|--------------|-------------|

| | |
|------------------|-----------------------|
| CSA087027 | PCR LATEX TEST |
|------------------|-----------------------|

Components:

| | |
|---------|------------------------|
| 151027A | PCR Regent |
| 151027B | PCR Controllo Positivo |
| 151027C | PCR Controllo Negativo |

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

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

- **1.1 Diagnostic Reagent**
- **Trade name:** PCR Regent
- **Article number:** 151027A
- **CAS Number:**
7732-18-5
- **EC number:**
231-791-2
- **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 substance 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

- **3.1 Substances**
- **CAS No. Description**
7732-18-5 water, distilled, conductivity or of similar purity
(Contd. on page 2)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Regent

(Contd. of page 1)

- **Identification number(s)**
- **EC number:** 231-791-2

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.
- **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 including amending Regulation
EU/2020/878

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Regent

(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:**
Not required.
- **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.
- **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** Liquid
- **Colour:** White
- **Odour:** Characteristic
- **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)
Not applicable.
- **Flammability**
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **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

(Contd. on page 4)

IE

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Regent

(Contd. of page 3)

- **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/cm³
- **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:** Not determined.
- **Explosive properties:** Product does not present an explosion hazard.
- **Solvent content:**
- **Water:** 100.0 %
- **VOC (EC)** 0.00 %
- **Solids content:** 0.0 %
- **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
- **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 including amending Regulation
EU/2020/878

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Regent

(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.
- **Primary irritant effect:**
- **Skin corrosion/irritation**
Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
- **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 including amending Regulation
EU/2020/878

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Regent

(Contd. of page 5)

- 12.7 Other adverse effects
- Additional ecological information:
- General notes: Not hazardous for water.

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 Substance is not 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.

(Contd. on page 7)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Regent

(Contd. of page 6)

- **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

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

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

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

- **1.1 Diagnostic Reagent**
- **Trade name:** PCR Controllo Positivo
- **Article number:** 151027B
- **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 substance 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
- **Additional information:**
Contains 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description**
Human Serum

(Contd. on page 2)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Positivo

(Contd. of page 2)

7 Handling and storage

- **7.1 Precautions for safe handling**
No special precautions are necessary if used correctly.
- **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.
- **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:**
Not required.
- **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:**
Wash hands before breaks and at the end of work.
- **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.
- **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** Liquid
- **Colour:** Not determined.
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.

(Contd. on page 4)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Positivo

(Contd. of page 3)

| | |
|----------------------------------------------------------------------------------------|-----------------------------------------------|
| • Boiling point or initial boiling point and boiling range | Undetermined. |
| • 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. |
| • Viscosity: | |
| • Kinematic viscosity | Not determined. |
| • Dynamic: | Not determined. |
| • Solubility | |
| • water: | Fully miscible. |
| • Partition coefficient n-octanol/water (log value) | Not determined. |
| • Vapour pressure: | Not determined. |
| • 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: | Not determined. |
| • Explosive properties: | Product does not present an explosion hazard. |
| • Solvent content: | |
| • 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 |

(Contd. on page 5)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Positivo

(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.
- **Primary irritant effect:**
- **Skin corrosion/irritation**
Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
- **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.

(Contd. on page 6)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Positivo

(Contd. of page 5)

- **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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**
Disposal must be made according to official regulations.
- **Recommended cleansing agents:**
Water, if necessary together with cleansing agents.

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 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Positivo

(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** Substance is not 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.

- **Relevant phrases**
 H301 Toxic if swallowed.
 H311 Toxic in contact with skin.
 H314 Causes severe skin burns and eye damage.
 H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H330 Fatal if inhaled.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.
 EUH071 Corrosive to the respiratory tract.
- **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
 Acute Tox. 3: Acute toxicity - Category 3

(Contd. on page 8)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Positivo

(Contd. of page 7)

Acute Tox. 2: Acute toxicity - Category 2

Skin Corr. 1B: Skin corrosion/irritation - Category 1B

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

Skin Sens. 1A: Skin sensitisation - Category 1A

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

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

IE

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

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

- **1.1 Diagnostic Reagent**
- **Trade name:** PCR Controllo Negativo
- **Article number:** 151027C
- **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 substance 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
- **Additional information:**
Contains 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description**
Animal Serum

(Contd. on page 2)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Negativo

(Contd. of page 2)

7 Handling and storage

- **7.1 Precautions for safe handling**
No special precautions are necessary if used correctly.
- **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.
- **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:**
Not required.
- **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:**
Wash hands before breaks and at the end of work.
- **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.
- **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** Liquid
- **Colour:** Not determined.
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.

(Contd. on page 4)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Negativo

(Contd. of page 3)

| | |
|----------------------------------------------------------------------------------------|-----------------------------------------------|
| • Boiling point or initial boiling point and boiling range | Undetermined. |
| • 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. |
| • Viscosity: | |
| • Kinematic viscosity | Not determined. |
| • Dynamic: | Not determined. |
| • Solubility | |
| • water: | Fully miscible. |
| • Partition coefficient n-octanol/water (log value) | Not determined. |
| • Vapour pressure: | Not determined. |
| • 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: | Not determined. |
| • Explosive properties: | Product does not present an explosion hazard. |
| • Solvent content: | |
| • 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 |

(Contd. on page 5)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Negativo

(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.
- **Primary irritant effect:**
- **Skin corrosion/irritation**
Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
- **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.

(Contd. on page 6)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Negativo

(Contd. of page 5)

- **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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**
Disposal must be made according to official regulations.
- **Recommended cleansing agents:**
Water, if necessary together with cleansing agents.

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 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Negativo

(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** Substance is not 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.

- **Relevant phrases**
 H301 Toxic if swallowed.
 H311 Toxic in contact with skin.
 H314 Causes severe skin burns and eye damage.
 H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H330 Fatal if inhaled.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.
 EUH071 Corrosive to the respiratory tract.
- **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
 Acute Tox. 3: Acute toxicity - Category 3

(Contd. on page 8)

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

Printing date 19.03.2025

Version number 1

Revision: 19.03.2025

Trade name: PCR Controllo Negativo

(Contd. of page 7)

Acute Tox. 2: Acute toxicity - Category 2

Skin Corr. 1B: Skin corrosion/irritation - Category 1B

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

Skin Sens. 1A: Skin sensitisation - Category 1A

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

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

IE