



24.06.2024

Kit Components

Product code	Description
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CSI087203	S. Typhi antigen H - Tube test
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Components:

392500	Sospensione S. Typhi antigen H
392073	Tampone PBS pH 7.2

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

Printing date 24.06.2024

Version number 1

Revision: 24.06.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Sospensione S. Typhi antigen H
- **Article number:** 392500
- **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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Sospensione S. Typhi antigen H

(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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Sospensione S. Typhi antigen H

(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** 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.
- **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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: *Sospensione S. Typhi antigen H*

(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:** 98.9 %
- **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
- **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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Sospensione S. Typhi antigen H

(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 including amending Regulation
EU/2020/878

Printing date 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Sospensione S. Typhi antigen H

(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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Sospensione S. Typhi antigen H

(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:** -

• **Date of previous version:** 03.04.2024

• **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

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

• *** Data compared to the previous version altered.**

IE

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

Printing date 24.06.2024

Version number 1

Revision: 24.06.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Tampone PBS pH 7.2
- **Article number:** 392073
- **CAS Number:**
7732-18-5
- **EC number:**
231-791-2
- **UFI:** U5W0-X0V5-T00A-M92V
- **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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Tampone PBS pH 7.2

(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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Tampone PBS pH 7.2

(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** 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.
- **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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Tampone PBS pH 7.2

(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/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: | Not determined. |
| • Explosive properties: | Product does not present an explosion
hazard. |
| • Solvent content: | |
| • Water: | 98.9 % |
| • 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 |
| • 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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Tampone PBS pH 7.2

(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 including amending Regulation
EU/2020/878

Printing date 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Tampone PBS pH 7.2

(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 24.06.2024

Version number 1

Revision: 24.06.2024

Trade name: Tampone PBS pH 7.2

(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:** -

• **Date of previous version:** 13.12.2023

• **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

• *** Data compared to the previous version altered.**

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