

24.06.2024 Kit Components

Product code	Description

CSI087244 TPHA / TPHA	
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Components:

151244 A	Test Cells - TPHA
151244 B	Control Cells - TPHA
151244 C	Diluente - TPHA
151244 D	Controllo Positivo - TPHA
181244 E	Controllo Negativo - TPHA



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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: Test Cells - TPHA

· Article number: 151244 A

· 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
- \cdot 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
- \cdot Classification according to Regulation (EC) No 1272/2008

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.

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≥0.25-<2.5%

Safety data sheet

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

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· vPvB: Not applicable.

3 Composition/information on ingredients

· 3.1 Substances

· CAS No. Description

7732-18-5 water, distilled, conductivity or of similar purity

· Identification number(s)

• **EC** number: 231-791-2

· Dangerous components:

EINECS: 247-852-1

CAS: 26628-22-8 sodium azide

♠ Acute Tox. 2, H300; Acute Tox. 1, H310; ♠ Aquatic Acute 1, H400;

Aquatic Chronic 1, H410, EUH032

4 First aid measures

- · 4.1 Description of first aid measures
- · 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

No further relevant information available.

5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

 \cdot 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:

Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system.

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).

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

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Dispose contaminated material as waste according to section 13.

· 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 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

 \cdot Ingredients with limit values that require monitoring at the workplace:

26628-22-8 sodium azide

OEL Short-term value: 0.3 mg/m³
Long-term value: 0.1 mg/m³
Skin, IOELV

· 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.

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

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Trade name: Test Cells - TPHA

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· 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
Colour:
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
 Dynamic at 20 °C:
 Not determined.
 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:
 Relative density
 Vapour density
 Not determined.
 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: 99.1 %
 VOC (EC) 0.00 %
 Solids content: 0.0 %
 Molecular weight 18.02 q/mol

· Change in condition

· Evaporation rate Not determined.

 Information with regard to physical hazard classes

• Explosives Void• Flammable gases Void

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

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Trade name: Test Cells - TPHA

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· 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.
- · 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	2,842 mg/kg			
Dermal	LD50	2,105 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.

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

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Trade name: Test Cells - TPHA

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· 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.

- · 12.7 Other adverse effects
- · Remark: Harmful to fish
- · 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.

Harmful to aquatic organisms

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.

· Europ	ean waste catalogue
HP6	Acute Toxicity
HP14	Ecotoxic

- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

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

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· Recommended cleansing agents:

Water, if necessary together with cleansing agents.

14 Transport information

14	1 IIN	number	or	TD	number
<i></i>	L OIV	numer	$O_{\mathcal{L}}$	$_{I}$	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.
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · 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.

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

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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

- H300 Fatal if swallowed. H310 Fatal in contact with skin. H400 Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. H410 EUH032 Contact with acids liberates very toxic gas.
- · Department issuing SDS: Product safety department.
- · Contact: -
- · Date of previous version: 06.06.2023
- · 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) ${\it IMDG: International\ Maritime\ Code\ for\ Dangerous\ Goods}$ 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 ATE: Acute toxicity estimate values Acute Tox. 2: Acute toxicity - Category 2 Acute Tox. 1: Acute toxicity - Category 1 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard -Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard -Category 3

· * Data compared to the previous version altered.



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Revision: 24.06.2024

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

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

undertaking

· 1.1 Diagnostic Reagent

· Trade name: Control Cells - TPHA

· Article number: 151244 B

· 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
- \cdot 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
- \cdot Classification according to Regulation (EC) No 1272/2008

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the ${\it CLP}$ regulation.

- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional/ national/international regulations.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.

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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: Control Cells - TPHA

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≥0.25-<2.5%

· vPvB: Not applicable.

3 Composition/information on ingredients

· 3.1 Substances

· CAS No. Description

7732-18-5 water, distilled, conductivity or of similar purity

· Identification number(s)

• **EC** number: 231-791-2

· Dangerous components:

EINECS: 247-852-1

CAS: 26628-22-8 sodium azide

♠ Acute Tox. 2, H300; Acute Tox. 1, H310; ♠ Aquatic Acute 1, H400;

Aquatic Chronic 1, H410, EUH032

4 First aid measures

· 4.1 Description of first aid measures

· 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.

 \cdot 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:

Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system.

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).

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

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Dispose contaminated material as waste according to section 13.

· 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 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:
- \cdot 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

 \cdot Ingredients with limit values that require monitoring at the workplace:

26628-22-8 sodium azide

OEL Short-term value: 0.3 mg/m³
Long-term value: 0.1 mg/m³
Skin, IOELV

· 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.

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· 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
Colour:
Odour:
Odour threshold:
Fluid
Colourless
Odourless
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
 Dynamic at 20 °C:
 Not determined.
 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:
 Relative density
 Vapour density
 Not determined.
 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: 99.1 %
 VOC (EC) 0.00 %
 Solids content: 0.0 %
 Molecular weight 18.02 q/mol

· Change in condition

· Evaporation rate Not determined.

 Information with regard to physical hazard classes

• Explosives Void• Flammable gases Void

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· Aerosols	Void	
· Oxidising gases	Void	
· Gases under pressure	Void	
\cdot 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 contac	t	
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.
- · 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 (Ac	ute To	xicity	Estimates)	
Oral	LD50	2,842	mg/kg	
Dermal	LD50	2 , 105	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.

(Contd. on page 6)

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: Control Cells - TPHA

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· 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.

- · 12.7 Other adverse effects
- · Remark: Harmful to fish
- · 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.

Harmful to aquatic organisms

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.

· Europ	ean waste catalogue
HP6	Acute Toxicity
HP14	Ecotoxic

- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

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

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Trade name: Control Cells - TPHA

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· Recommended cleansing agents:

Water, if necessary together with cleansing agents.

14 Transport information

14 1	TTN	number	or	תד	number
<i></i>	011	number	O_{\perp}	$\perp \nu$	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.
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · 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.

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

Version number 1 Revision: 24.06.2024 Printing date 24.06.2024

Trade name: Control Cells - TPHA

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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

- H300 Fatal if swallowed. H310 Fatal in contact with skin. H400 Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. H410 EUH032 Contact with acids liberates very toxic gas.
- · Department issuing SDS: Product safety department.

· * Data compared to the previous version altered.

- · Contact: -
- · Date of previous version: 06.06.2023
- · 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) ${\it IMDG: International\ Maritime\ Code\ for\ Dangerous\ Goods}$ 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 ATE: Acute toxicity estimate values Acute Tox. 2: Acute toxicity - Category 2 Acute Tox. 1: Acute toxicity - Category 1 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard -Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard -Category 3

TE -



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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: Diluente - TPHA

· Article number: 151244 C

· 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)

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

Version number 1 Revision: 24.06.2024 Printing date 24.06.2024

Trade name: Diluente - TPHA

(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.
- \cdot 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)

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: Diluente - TPHA

(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
 Colour:
 Colourless
 Odour:
 Odourless

· Odour threshold: Not determined.

• Melting point/freezing point: 0 °C

· Boiling point or initial boiling

· 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
 Dynamic at 20 °C:
 Not determined.
 0.952 mPas

(Contd. on page 4)

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: Diluente - TPHA

(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: 1.00804 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: 99.8 % · Water: · VOC (EC) 0.00 % · Solids content: 0.0 % 18.02 g/mol · Molecular weight · 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 Void · Corrosive to metals · Desensitised explosives Void

10 Stability and reactivity

· 10.1 Reactivity No further relevant information available.

(Contd. on page 5)

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: Diluente - TPHA

(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

- \cdot 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)

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: Diluente - TPHA

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- · 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 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

- \cdot 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)

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: Diluente - TPHA

(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 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: -
- · Date of previous version: 06.06.2023
- · 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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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

/minture and of the company/

Revision: 24.06.2024

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

- · 1.1 Diagnostic Reagent
- · Trade name: Controllo Positivo TPHA
- · Article number: 151244 D
- · 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

- \cdot 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)

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: Controllo Positivo - TPHA

(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.
- \cdot 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)

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: Controllo Positivo - TPHA

(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: Light yellowOdour: OdourlessOdour 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)

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: Controllo Positivo - TPHA

	(Contd. of page	
Flash point:	Not applicable.	
Decomposition temperature:	Not determined.	
pH at 20 °C	7.2	
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,	
1	conductivity or of similar purity)	
Density and/or relative density	1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1	
Density at 20 °C:	1.00804 g/cm^3	
Relative density	Not determined.	
Bulk density:	1,008 kg/m³	
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 explosic	
	hazard.	
Solvent content:		
Water:	94.6 %	
VOC (EC)	0.00 %	
Solids content:	0.0 %	
Change in condition		
Change in condition		
Evaporation rate	Not determined.	
Evaporation rate	Not determined.	
Evaporation rate Information with regard to	Not determined.	
Evaporation rate Information with regard to physical hazard classes	Not determined.	
Evaporation rate Information with regard to physical hazard classes Explosives		
Evaporation rate Information with regard to physical hazard classes Explosives Flammable gases	Void Void	
Evaporation rate Information with regard to physical hazard classes Explosives Flammable gases Aerosols	Void Void Void	
Evaporation rate Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases	Void Void Void Void	
Evaporation rate Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure	Void Void Void Void Void	
Evaporation rate Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids	Void Void Void Void Void Void	
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Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which	Void Void Void Void Void Void Void Void	
Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures Substances and mixtures, which emit flammable gases in contact	Void Void Void Void Void Void Void Void	
Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures Substances and mixtures Substances and mixtures which emit flammable gases in contact with water	Void Void Void Void Void Void Void Void	
Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures Substances and mixtures Substances and mixtures Oxidising liquids	Void Void Void Void Void Void Void Void	
Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water Oxidising liquids Oxidising solids	Void Void Void Void Void Void Void Void	
Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures Substances and mixtures Substances and mixtures Oxidising liquids	Void Void Void Void Void Void Void Void	

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: Controllo Positivo - TPHA

(Contd. of page 4)

· Desensitised explosives

Void

10 Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- \cdot Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- \cdot 10.3 Possibility of hazardous reactions No dangerous reactions known.
- \cdot 10.4 Conditions to avoid No further relevant information available.
- \cdot 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.

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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: Controllo Positivo - TPHA

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- · 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

• 1	4.1	UN	number	or	ID	number
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· 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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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: Controllo Positivo - TPHA

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15 Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This Safety Data 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: -
- · Date of previous version: 06.06.2023
- · 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

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

· * Data compared to the previous version altered.

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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: Controllo Negativo TPHA
- · Article number: 181244 E
- \cdot 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

- \cdot 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

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

3 Composition/information on ingredients

- · 3.2 Mixtures
- · Description:

Mixture of substances listed below with nonhazardous additions.

· Dangerous components: Void

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

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· Additional information:

For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- · After inhalation:

Supply fresh air; consult doctor in case of complaints.

- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact:

Rinse opened eye for several minutes under running water.

- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

- · 5.2 Special hazards arising from the substance or mixture
 No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection:

No special measures required.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.

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

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Trade name: Controllo Negativo - TPHA

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

8 Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:
 The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- · Additional information:

The lists valid during the making were used as basis.

- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

- · Respiratory protection: Not required.
- · Hand protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection Goggles recommended during refilling

9 Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information

· Physical state Fluid

Colour: Light yellowOdour: OdourlessOdour threshold: Not determined.

• Melting point/freezing point: 0 °C

· Boiling point or initial boiling

point and boiling range
100 °C (7732-18-5 water, distilled,

conductivity or of similar purity)

· Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.Upper: Not determined.

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Trade name: Controllo Negativo - TPHA

	(Contd. of page
Flash point:	Not applicable.
Decomposition temperature:	Not determined.
pH at 20 °C	7.2
Viscosity:	/ • Z
Kinematic viscosity	Not determined.
Dynamic at 20 °C:	0.952 mPas
Solubility	0.932 MFaS
water:	Eully missible
<pre>Partition coefficient n-octanol/</pre>	Fully miscible.
•	
water (log value)	Not determined.
Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled,
D	conductivity or of similar purity)
Density and/or relative density	1 00004 / 3
Density at 20 °C:	1.00804 g/cm³
Relative density	Not determined.
Bulk density:	1,008 kg/m³
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
impleative properties.	hazard.
Solvent content:	iidZdId.
Water:	94.6 %
VOC (EC)	0.00 %
Solids content:	0.0 %
	0.0 6
Change in condition	Not determined.
William Craft Craft	
Evaporation rate	NOT decemment.
Information with regard to	Not determined.
Information with regard to physical hazard classes	
Information with regard to physical hazard classes Explosives	Void
Information with regard to physical hazard classes Explosives Flammable gases	Void Void
Information with regard to physical hazard classes Explosives Flammable gases Aerosols	Void
Information with regard to physical hazard classes Explosives Flammable gases	Void Void
Information with regard to physical hazard classes Explosives Flammable gases Aerosols	Void Void Void
Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases	Void Void Void Void
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Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids	Void Void Void Void Void Void
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Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water	Void Void Void Void Void Void Void Void
Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water Oxidising liquids	Void Void Void Void Void Void Void Void
Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water	Void Void Void Void Void Void Void Void
Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water Oxidising liquids	Void Void Void Void Void Void Void Void

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

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Trade name: Controllo Negativo - TPHA

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· Desensitised explosives

Void

10 Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- \cdot Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- \cdot 10.4 Conditions to avoid No further relevant information available.
- \cdot 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.

(Contd. on page 6)

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: Controllo Negativo - TPHA

(Contd. of page 5)

- · 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

٠	14.1	UN number or ID number
٠	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
- Class

· 14.4 Packing group

· ADR, IMDG, IATA

not regulated

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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Trade name: Controllo Negativo - TPHA

(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.

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- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

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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.

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