

| 20.03.2025 | Kit Components |
|------------|----------------|
| | |

| | <u> </u> | | |
|--------------|-----------------------------------|--|--|
| Product code | Description | | |
| | | | |
| B78282280 | IMMUNOGLOBULINE G URINARIE (ULGG) | | |
| Components: | | | |
| 282143 | IGG totali urinarie lattice Bulk | | |
| 282140 | Tampone urinarie Bulk | | |



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Revision: 20.03.2025

Safety data sheet

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

Printing date 20.03.2025

undertaking

Version number 1

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

- · 1.1 Diagnostic Reagent
- · Trade name: IGG totali urinarie lattice Bulk
- · Article number: 282143
- · 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:

CAS: 57-50-1 sucrose, pure

EINECS: 200-334-9 substance with a Community workplace

exposure limit

>10-**≤**25%

(Contd. on page 2)

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:
- \cdot 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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- · 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:

57-50-1 sucrose, pure

OEL Short-term value: 20 mg/m³ Long-term value: 10 mg/m³

· Additional information:

The lists valid during the making were used as basis.

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

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

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

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

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

· Material of gloves

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

· Penetration time of glove material

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

· Eye/face protection Goggles recommended during refilling

9 Physical and chemical properties

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

Physical state
 Colour:
 White
 Odour:
 Odourless
 Odour threshold:
 Melting point/freezing point:
 Undetermined.

· Boiling point or initial boiling

· Flammability Not applicable.

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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: IGG totali urinarie lattice Bulk

| | (Contd. of pag |
|--|-------------------------------------|
| Lower and upper explosion limit | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| Flash point: | Not applicable. |
| Decomposition temperature: | Not determined. |
| pH at 20 °C | 7.4 |
| Viscosity: | |
| Kinematic viscosity | Not determined. |
| Dynamic: | Not determined. |
| Solubility | |
| water: | Fully miscible. |
| Partition coefficient n-octanol/ | |
| water (log value) | Not determined. |
| Vapour pressure at 20 °C: | 23 hPa (7732-18-5 water, distilled, |
| 1 | conductivity or of similar purity) |
| Density and/or relative density | comadocivio, or or similar pario, |
| Density: | Not determined. |
| Relative density | Not determined. |
| Vapour density | Not determined. |
| | NOT ACCCIMINGA. |
| 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 explosi |
| | hazard. |
| Solvent content: | |
| Water: | 80.1 % |
| VOC (EC) | 0.00 % |
| Solids content: | 0.2 % |
| Change in condition | |
| Evaporation rate | Not determined. |
| Information with regard to | |
| nnrormation with regard to physical hazard classes | |
| | Void |
| 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 |
| with water | |
| | Void |
| Oxidising liquids | 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: IGG totali urinarie lattice Bulk

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Corrosive to metalsDesensitised explosivesVoid

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:
 - 57-50-1 sucrose, pure

Oral LD50 29,700 mg/kg (rat)

- · Primary irritant effect:
- · Skin corrosion/irritation

Based on available data, the classification criteria are not met.

· Serious eye damage/irritation

Based on available data, the classification criteria are not met.

· Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

· Germ cell mutagenicity

Based on available data, the classification criteria are not met.

· Carcinogenicity

Based on available data, the classification criteria are not met.

· Reproductive toxicity

Based on available data, the classification criteria are not met.

· STOT-single exposure

Based on available data, the classification criteria are not met.

· STOT-repeated exposure

Based on available data, the classification criteria are not met.

 \cdot 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.

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

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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.
- \cdot 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Smaller quantities can be disposed of with household waste.

- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

· Recommended cleansing agents:

Water, if necessary together with cleansing agents.

14 Transport information

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

according to IMO instruments Not applicable.

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

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· UN "Model Regulation": not regulated

15 Regulatory information

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

- · Department issuing SDS: Product safety department.
- · Contact: -
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative



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Safety data sheet

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

Printing date 20.03.2025

Version number 1

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

- · 1.1 Diagnostic Reagent
- · Trade name: Tampone urinarie Bulk
- · Article number: 282140
- **UFI:** TGM0-U052-V00A-TT7C
- 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant Identified Uses: For laboratory use only Uses advised against: Uses other than those recommended

- · Application of the substance / the mixture Diagnostic reagent
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Sclavo Diagnostics International Via Po 26-28, Loc. Pian dei Mori CAP: 53018 - SOVICILLE - (SI) ITALY

- · Further information obtainable from: Product safety department.
- 1.4 Emergency telephone number: +39 0577 390 444 / 445

2 Hazards identification

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

 The product is not classified, according to the CLP regulation.
- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Additional information:

Contains Gentamicin. May produce an allergic reaction. Safety data sheet available on request.

- · 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.

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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: Tampone urinarie Bulk

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· Dangerous components:

1405-41-0 Gentamicin (*) Skin Sens. 1A, H317 <0.1%

· Additional information:

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

4 First aid measures

- \cdot 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:

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 precautions are necessary if used correctly.

· Information about fire - and explosion protection:

No special measures required.

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Trade name: Tampone urinarie Bulk

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- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

No special requirements.

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

8 Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace: 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:

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. 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
 Colour:
 Odour:
 Odourless
 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.

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Trade name: Tampone urinarie Bulk

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|---|--|
| Tarray and reman armitation limit | (Contd. of page |
| Lower and upper explosion limit | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| Flash point: | Not applicable. |
| Decomposition temperature: | Not determined. |
| pH at 20 °C | 8.3 |
| Viscosity: | |
| Kinematic viscosity | Not determined. |
| Dynamic at 20 °C: | 0.952 mPas |
| Solubility | |
| water: | Fully miscible. |
| Partition coefficient n-octanol, | |
| water (log value) | Not determined. |
| Vapour pressure at 20 °C: | 23 hPa (7732-18-5 water, distilled, |
| | conductivity or of similar purity) |
| Density and/or relative density | |
| Density at 20 °C: | 1 g/cm³ |
| Relative density | Not determined. |
| Vapour density | Not determined. |
| | The descrimination. |
| 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: | 95.6 % |
| VOC (EC) | 0.00 % |
| Solids content: | 0.6 % |
| Molecular weight | 18.02 g/mol |
| Change in condition | - · · · · · · · · · · · · · · · · · · · |
| | |
| = | Not determined. |
| Evaporation rate | Not determined. |
| Evaporation rate Information with regard to | Not determined. |
| Evaporation rate Information with regard to physical hazard classes | |
| Evaporation rate Information with regard to physical hazard classes Explosives | Void |
| 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 |
| Evaporation rate Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids | Void Void Void Void Void |
| Information rate Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and | Void Void Void Void Void Void |
| Information rate 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 | Void Void Void Void Void Void |
| Information rate 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 | Void Void Void Void Void Void Void |
| Information rate 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 | 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 | Void Void Void Void Void Void Void Void |
| Information rate Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and | 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 | 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 | 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 | 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 |

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Trade name: Tampone urinarie Bulk

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Organic peroxides
 Corrosive to metals
 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.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products:

No dangerous decomposition products known.

11 Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity

Based on available data, the classification criteria are not met.

- · Primary irritant effect:
- · Skin corrosion/irritation

Based on available data, the classification criteria are not met.

· Serious eye damage/irritation

Based on available data, the classification criteria are not met.

· Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

· Germ cell mutagenicity

Based on available data, the classification criteria are not met.

· Carcinogenicity

Based on available data, the classification criteria are not met.

· Reproductive toxicity

Based on available data, the classification criteria are not met.

· STOT-single exposure

Based on available data, the classification criteria are not met.

· STOT-repeated exposure

Based on available data, the classification criteria are not met.

· Aspiration hazard

Based on available data, the classification criteria are not met.

- · 11.2 Information on other hazards
- · Endocrine disrupting properties

The product contains substances, which affect the thyroid system and other hormonal systems.

None of the ingredients is listed.

12 Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability

No further relevant information available.

(Contd. on page 6)

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

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· 12.3 Bioaccumulative potential

No further relevant information available.

- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

· Recommended cleansing agents:

Water, if necessary together with cleansing agents.

14 Transport information

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

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

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Trade name: Tampone urinarie Bulk

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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

7647-01-0 hydrogen chloride

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

7647-01-0 hydrogen chloride

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· 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Other information

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

This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· Relevant phrases

H317 May cause an allergic skin reaction.

- · Department issuing SDS: Product safety department.
- · Contact: -
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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