

|               |  |                      |                  |
|---------------|--|----------------------|------------------|
| Trading name: | <b>GRAM LUGOL SOLUTION, STABILIZED</b> |                      |                  |
| Product code: | GLS-OT-X**                             | Date of compilation: | 14 November 2022 |
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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

|      |   |   |
|------|---|---|
| 1.1. | Product identifier  |   |
|      | Trading name:   | GRAM LUGOL SOLUTION, STABILIZED   |
|      | Chemical name:  | -   |
|      | Catalogue number:   | GLS-OT-X**  |
| 1.2. | Relevant identified uses of the substance or mixture and uses advised against |   |
|      | Uses:   | Solution for use in BioGram 4 Gram bacteria staining kit.   |
|      | Uses advised against:   | Only the identified uses are advised.   |
|      | Reason why uses advised against:  | The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes |
| 1.3. | Details of the supplier of the safety data sheet                              |   |
|      | Supplier:   | BioGnost Ltd.   |
|      | Address:  | Medjugorska 59, Zagreb  |
|      | Telephone number:   | +385 1 2409997  |
|      | Fax no.:  | +385 1 2404039  |
|      | e-mail of competent person:   | <a href="mailto:msds@biognost.hr">msds@biognost.hr</a>  |
|      | National contact:   | -   |
| 1.4. | Emergency telephone number  |   |
|      | National Protection and Rescue Directorate:                                   | 112   |
|      | Medical information:  | +385 1 2348 342   |
|      | Other information:  | -   |

### SECTION 2. Hazards identification

|  |  |                                 |
|--|--|---------------------------------|
| 2.1.   | Classification of the substance or mixture                     |                                 |
| 2.1.1.   | Classification according to Regulation (EC) No 1272/2008 (CLP) |                                 |
|  | Hazard class and category code:                                | Hazard statements*:             |
|  | Not identified as hazardous substance.                         | -                               |
| 2.1.2.   | Additional information   |                                 |
|  | -  |                                 |
| *For full text of Hazard- and EU Hazard-statements: see Section 16 |  |                                 |
| 2.2.   | Label elements   |                                 |
|  | Product identification:  | GRAM LUGOL SOLUTION, STABILIZED |
|  | Identification number:   | -                               |
|  | Authorization no.:   | -                               |
|  | Hazard pictograms:   | -                               |

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|                                       |   |
|---------------------------------------|---|
| Signal word:                          | - |
| Hazard statements:                    | - |
| Precautionary statements:             | - |
| Supplemental hazard information (EU): | - |

|      |  |
|------|--|
| 2.3. | Other hazards  |
|      | <b>Endocrine Disrupting Properties:</b><br>No known endocrine disrupting properties. |

**SECTION 3. Composition/information on ingredients**

| CAS/EC/ Index no. | REACH Registration No | Weight % content (or range) | Identification name              | Classification according to Regulation (EC) No 1272/2008 (CLP) |
|-------------------|-----------------------|-----------------------------|----------------------------------|--|
| -                 | -                     | -                           | Contains no hazardous substances | -  |

**SECTION 4. First aid measures**

|      |   |   |
|------|---|---|
| 4.1. | Description of first aid measures                           |   |
|      | General notes:  | -   |
|      | Following inhalation:                                       | Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician. |
|      | Following skin contact:                                     | Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.   |
|      | Following eye contact:                                      | Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.  |
|      | Following ingestion:  | Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.                                   |
|      | Self-protection of the first aider:                         | Treat symptomatically.  |
| 4.2. | Most important symptoms and effects, both acute and delayed |   |
|      | Following inhalation:                                       | According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.  |
|      | Following skin contact:                                     | According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.  |
|      | Following eye contact:                                      | According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.  |

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|------|--|--|
|      | Following ingestion:   | According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested. |
| 4.3. | Indication of any immediate medical attention and special treatment needed |  |
|      | -  |  |

|   |   |   |
|---|---|---|
| <b>SECTION 5. Firefighting measures</b> |   |   |
| 5.1.                                    | Extinguishing media   |   |
|   | Suitable extinguishing media:   | Small fire - water spray, dry powder, CO <sub>2</sub><br>Large fire - water spray or alcohol-resistant foam |
|   | Unsuitable extinguishing media:   | water jet   |
| 5.2.                                    | Special hazards arising from the substance or mixture   |   |
|   | Hazardous combustion products:  | No information available  |
| 5.3.                                    | Advice for firefighters   |   |
|   | Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.<br>Cool closed containers exposed to fire with water spray or vapor. |   |
| 5.4.                                    | Additional information  |   |
|   | Remove sources of heat and ignition.<br>Do not contaminate the environment with extinguishing media.  |   |

|   |   |  |
|---|---|--|
| <b>SECTION 6. Accidental release measures</b> |   |  |
| 6.1.  | Personal precautions, protective equipment and emergency procedures   |  |
| 6.1.1.  | For non-emergency personnel   |  |
|   | Protective equipment:   | Use personal protective equipment (see Section 8).   |
|   | Accident prevention methods:  | Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke. |
|   | Emergency procedures:   | Mark the area using proper signs.  |
| 6.1.2.  | For emergency responders:   |  |
|   | Wear protective equipment (see Section 8).  |  |
| 6.2.  | Environmental precautions:  |  |
|   | Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112. |  |
| 6.3.  | Methods and material for containment and cleaning up  |  |
| 6.3.1.  | Bundling, covering of drains; capping procedures:   | Sand or clay barriers.   |

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|--------|---|---|
| 6.3.2. | Cleaning up:  | Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water. |
| 6.3.3. | Other information:  | -   |
| 6.4.   | Reference to other sections   |   |
|        | See Section 7 for information about secure handling.<br>See Section 8 for information about personal protective equipment.<br>See Section 13 for information about containment. |   |

|  |  |   |
|--|--|---|
| <b>SECTION 7. Handling and storage</b> |  |   |
| 7.1.                                   | Precautions for safe handling  |   |
| 7.1.1.                                 | Protection measures  |   |
|  | Measures to prevent fire:  | Keep away from sources of heat and ignition. Do not smoke.  |
|  | Measures to prevent aerosol and dust generation:   | Secure proper ventilation.  |
|  | Measures to protect the environment:   | Prevent spilling into the sewage system and waterways.  |
|  | Other measures:  | -   |
| 7.1.2.                                 | Advice on general occupational hygiene:  |   |
|  | Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating. |   |
| 7.2.                                   | Conditions for safe storage, including any incompatibilities                                     |   |
|  | Technical measures and storage conditions:   | Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.           |
|  | Packaging materials:   | Manufacturer's original packaging.  |
|  | Requirements for storage rooms and vessels:  | Keep away from food and drink. Keep the containers tightly closed.  |
|  | Advices for storage equipment:   | The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation. |
|  | Further information on storage conditions:   | Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9). |
| 7.3.                                   | Specific end use(s)  |   |

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|                                       |   |
|---------------------------------------|---|
| Recommendations:                      | - |
| Industrial sector specific solutions: | - |

**SECTION 8. Exposure controls/personal protection**

**8.1. Control parameters**

| Substance | CAS No | Occupational exposure limit values/short term values |                   | Biological limit values  |
|-----------|--------|--|-------------------|--------------------------|
|           |        | ppm  | mg/m <sup>3</sup> |                          |
| -         | -      | -  | -                 | No information available |

Substance name: -

EC No: - CAS No: -

**DNEL**

**Industrial**

| Route of exposure: | Acute effect local | Acute effect systemic | Chronic effect local | Chronic effect systemic |
|--------------------|--------------------|-----------------------|----------------------|-------------------------|
| Oral               | -                  | -                     | -                    | -                       |
| Inhalation         | -                  | -                     | -                    | -                       |
| Dermal             | -                  | -                     | -                    | -                       |

Critical physical parameters: solubility, flammability, corrosivity: -

**Consumer**

| Route of exposure: | Acute effect local | Acute effect systemic | Chronic effect local | Chronic effect systemic |
|--------------------|--------------------|-----------------------|----------------------|-------------------------|
| Oral               | -                  | -                     | -                    | -                       |
| Inhalation         | -                  | -                     | -                    | -                       |
| Dermal             | -                  | -                     | -                    | -                       |

**PNEC**

| Environmental protection target    | PNEC                     |
|------------------------------------|--------------------------|
| Fresh water                        | No information available |
| Freshwater sediments               | No information available |
| Marine water                       | No information available |
| Marine sediments                   | No information available |
| Food chain                         | No information available |
| Microorganisms in sewage treatment | No information available |
| Soil (agricultural)                | No information available |

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|----------|--|--|
| Air      | No information available   |  |
| 8.2.     | Exposure controls  |  |
| 8.2.1.   | Appropriate engineering controls   |  |
|          | Substance/mixture related measures to prevent exposure during identified uses: | Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.  |
|          | Structural measures to prevent exposure:                                       | No information available   |
|          | Organisational measures to prevent exposure:                                   | Organization of work in order to reduce other worker's influence during work process.  |
|          | Technical measures to prevent exposure:  | Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.   |
| 8.2.2.   | Personal protection equipment  |  |
| 8.2.2.1. | Eye and face protection:   | Safety glasses that stick to face (preventing splashing) (EN 166) or visor.  |
| 8.2.2.2. | Skin protection  |  |
|          | Hand protection:   | Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374.<br>Glove material: nitrile rubber<br>Glove thickness: ≥0.50 mm<br>Break through time: >480 min             |
|          | Other skin protection:   | Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).  |
| 8.2.2.3. | Respiratory protection:  | Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI. |
| 8.2.2.4. | Thermal hazards:   | No information available   |
| 8.2.3.   | Environmental exposure controls  |  |
|          | Substance/mixture related measures to prevent exposure:                        | See Section 6  |
|          | Structural measures to prevent exposure:                                       | Use modern equipment.  |
|          | Organisational measures to prevent exposure:                                   | Adapt the work process to the required working conditions of the workplace.  |
|          | Technical measures to prevent exposure:  | See Section 6  |

**SECTION 9. Physical and chemical properties**

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| 9.1. Information on basic physical and chemical properties |   |                                  |                          |
|--|---|----------------------------------|--------------------------|
|  |   | Value                            | Method                   |
|  | Physical state:   | liquid                           | No information available |
|  | Color:  | yellow/amber                     | No information available |
|  | Odour/odour threshold:                                    | no odor/no information available | No information available |
|  | Melting point / freezing point:                           | No information available         | No information available |
|  | Boiling point or initial boiling point and boiling range: | No information available         | No information available |
|  | Flammability:   | No information available         | No information available |
|  | Lower and upper explosion limit:                          | No information available         | No information available |
|  | Flash point:  | No information available         | No information available |
|  | Auto-ignition temperature:                                | No information available         | No information available |
|  | Decomposition temperature:                                | No information available         | No information available |
|  | pH:   | No information available         | No information available |
|  | Kinematic viscosity:                                      | No information available         | No information available |
|  | Solubility:   | No information available         | No information available |
|  | Partition coefficient n-octanol/water (log value):        | No information available         | No information available |
|  | Vapour pressure:  | No information available         | No information available |
|  | Density and/or relative density                           | No information available         | No information available |
|  | Relative vapour density:                                  | No information available         | No information available |
|  | Particle characteristics:                                 | No information available         | No information available |
| 9.2. Other information                                     |   |                                  |                          |
|  | -   |                                  |                          |

| SECTION 10.: Stability and reactivity |                                     |  |
|---------------------------------------|-------------------------------------|--|
| 10.1.                                 | Reactivity:                         | See subsections 10.3 through 10.5.   |
| 10.2.                                 | Chemical stability:                 | The product is chemically stable under standard ambient conditions of storing and using. |
| 10.3.                                 | Possibility of hazardous reactions: | No information available.  |
| 10.4.                                 | Conditions to avoid:                | No information available.  |
| 10.5.                                 | Incompatible materials:             | No information available.  |
| 10.6.                                 | Hazardous decomposition products:   | No information available.  |

| SECTION 11. Toxicological information |
|---------------------------------------|
|---------------------------------------|

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|--|--|---------|---|---------------|---------|
| 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 |  |         |   |               |         |
| Acute toxicity:  |  |         |   |               |         |
| Route of exposure:   | Method   | Species | Effective Dose<br>LD <sub>50</sub> /LC <sub>50</sub> or<br>ATE <sub>mixture</sub> | Exposure time | Results |
| Oral exposure:   | No information available   | -       | LD <sub>50</sub>  | -             | -       |
| Dermal exposure:   | No information available   | -       | LD <sub>50</sub>  | -             | -       |
| Inhalation exposure:   | No information available   | -       | LC <sub>50</sub>  | -             | -       |
| Specific target organ toxicity – single exposure (STOT SE):                    |  |         |   |               |         |
|  | Specific effects   |         | Target organ  |               | Note    |
| Oral exposure:   | No information available   |         | No information available  |               | -       |
| Dermal exposure:   | No information available   |         | No information available  |               | -       |
| Inhalation exposure:   | No information available   |         | No information available  |               | -       |
| Aspiration hazard: No information available                                    |  |         |   |               |         |
| Irritation and corrosion:  |  |         |   |               |         |
|  | Exposure time  | Species | Evaluation  | Method        | Note    |
| Skin irritation:   | -  | -       | -   | -             | -       |
| Eye irritation:  | -  | -       | -   | -             | -       |
| Sensitization  |  |         |   |               |         |
| Dermal exposure:   | No information available   |         |   |               |         |
| Inhalation exposure:   | No information available   |         |   |               |         |
| Symptoms related to the physical, chemical and toxicological characteristics   |  |         |   |               |         |
| Oral exposure:   | According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested. |         |   |               |         |
| Dermal exposure:   | According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested. |         |   |               |         |
| Inhalation exposure:   | According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested. |         |   |               |         |



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|---------------|--|
| Eye exposure: | According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested. |
|---------------|--|

|  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|
| Repeated dose toxicity (subacute, subchronic, chronic) |  |  |  |  |  |  |
|--|--|--|--|--|--|--|

|                       | Dose                     | Exposure time            | Species                  | Method                   | Evaluation               | Note |
|-----------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|------|
| Subacute oral         | No information available | No information available | No information available | No information available | No information available | -    |
| Subacute dermal       | No information available | No information available | No information available | No information available | No information available | -    |
| Subacute inhalation   | No information available | No information available | No information available | No information available | No information available | -    |
| Subchronic oral       | No information available | No information available | No information available | No information available | No information available | -    |
| Subchronic dermal     | No information available | No information available | No information available | No information available | No information available | -    |
| Subchronic inhalation | No information available | No information available | No information available | No information available | No information available | -    |
| Chronic oral          | No information available | No information available | No information available | No information available | No information available | -    |
| Chronic dermal        | No information available | No information available | No information available | No information available | No information available | -    |
| Chronic inhalation    | No information available | No information available | No information available | No information available | No information available | -    |

|   |  |  |  |
|---|--|--|--|
| Specific target organ toxicity – repeated exposure (STOT RE): |  |  |  |
|---|--|--|--|

|                     | Specific effects         | Target organ             | Note |
|---------------------|--------------------------|--------------------------|------|
| Subacute oral       | No information available | No information available | -    |
| Subacute dermal     | No information available | No information available | -    |
| Subacute inhalation | No information available | No information available | -    |
| Subchronic oral     | No information available | No information available | -    |

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|-----------------------|--------------------------|--------------------------|---|
| Subchronic dermal     | No information available | No information available | - |
| Subchronic inhalation | No information available | No information available | - |
| Chronic oral          | No information available | No information available | - |
| Chronic dermal        | No information available | No information available | - |
| Chronic inhalation    | No information available | No information available | - |

|  |   |
|--|---|
| CMR effects (carcinogenicity; mutagenicity; reproductive toxicity) |   |
| Carcinogenicity:   | Current studies on test animals did not indicate carcinogenic effects.    |
| Mutagenicity <i>in-vitro</i> :                                     | Current <i>in vitro</i> tests did not indicate mutagenic effects.         |
| Genotoxicity:  | No information available  |
| Mutagenicity <i>in-vivo</i> :                                      | Current <i>in vivo</i> tests did not indicate mutagenic effects.          |
| Germ cell mutagenicity:  | No information available  |
| Reproductive toxicity:   | No toxicity on reproductive organs was determined in reproductive organs. |
| Summary of evaluation of the CMR properties: -                     |   |

|         |  |
|---------|--|
| 11.2.   | Information on other hazards:                                      |
| 11.2.1. | Endocrine disrupting properties:                                   |
|         | No known endocrine disrupting properties that affect human health. |
| 11.2.2. | Other information:   |
|         | -  |

**SECTION 12. Ecological information**

|                              |                  |               |                          |                          |            |      |
|------------------------------|------------------|---------------|--------------------------|--------------------------|------------|------|
| 12.1.                        | Toxicity         |               |                          |                          |            |      |
| Acute toxicity               | Dose             | Exposure time | Species                  | Method                   | Evaluation | Note |
| Fish                         | LC <sub>50</sub> | 96 hours      | No information available | No information available | -          | -    |
| Crustacea:                   | EC <sub>50</sub> | 48 hours      | No information available | No information available | -          | -    |
| Algae/aquatic plants         | IC <sub>50</sub> | 8 days        | No information available | No information available | -          | -    |
| Microorganisms               | LC <sub>50</sub> | 72 hours      | -                        | -                        | -          | -    |
| Chronic (long-term) toxicity | Dose             | Exposure time | Species                  | Method                   | Evaluation | Note |

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|----------------------|------------------|----------|--------------------------|--------------------------|--------------------------|---|
| Fish                 | LC <sub>50</sub> | 96 hours | No information available | No information available | No information available | - |
| Crustacea:           | EC <sub>50</sub> | 48 hours | No information available | No information available | No information available | - |
| Algae/aquatic plants | IC <sub>50</sub> | 72 hours | No information available | No information available | No information available | - |
| Other organisms      | -                | -        | -                        | -                        | -                        | - |

**12.2. Persistence and degradability**

Abiotic degradation

|              | Degradation half-lives   | Method                   | Evaluation               | Note |
|--------------|--------------------------|--------------------------|--------------------------|------|
| Marine water | No information available | No information available | No information available | -    |
| Fresh water  | No information available | No information available | No information available | -    |
| Air          | No information available | No information available | No information available | -    |
| Soil         | No information available | No information available | No information available | -    |

Biodegradation

| % Degradation            | Time (days)              | Method                   | Evaluation               | Note                     |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| No information available | No information available | No information available | No information available | No information available |
|                          |                          |                          |                          |                          |

**12.3. Bioaccumulative potential**

Octanol-water partition coefficient (log Kow)

| Value | Concentration            | pH | °C | Method                   | Evaluation               | Note |
|-------|--------------------------|----|----|--------------------------|--------------------------|------|
| -     | No information available | -  | -  | No information available | No information available | -    |
|       |                          |    |    |                          |                          |      |

Bioconcentration factor (BCF)

| Value | Species | Method | Evaluation | Note |
|-------|---------|--------|------------|------|
|-------|---------|--------|------------|------|

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|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| No information available | No information available | No information available | No information available | No information available |
|                          |                          |                          |                          |                          |

|  |                  |                          |                          |                          |                          |      |
|--|------------------|--------------------------|--------------------------|--------------------------|--------------------------|------|
| Chronic ecotoxicity                              |                  |                          |                          |                          |                          |      |
| Value  | Dose             | Exposure time            | Species                  | Method                   | Evaluation               | Note |
| Chronic toxicity on fish                         | LC <sub>50</sub> | No information available | No information available | No information available | No information available | -    |
| Chronic toxicity on crustacea ( <i>Daphnia</i> ) | EC <sub>50</sub> | No information available | No information available | No information available | No information available | -    |

**12.4. Mobility in soil**

|  |                          |                          |                          |      |  |  |
|--|--------------------------|--------------------------|--------------------------|------|--|--|
| Known or predicted distribution in environmental compartments: |                          |                          |                          |      |  |  |
| No information available                                       |                          |                          |                          |      |  |  |
| Surface tension:   |                          |                          |                          |      |  |  |
| Value  | °C                       | Concentration            | Method                   | Note |  |  |
| No information available                                       | No information available | No information available | No information available | -    |  |  |

**Adsorption / desorption**

|            |                                     |                          |                          |                          |      |
|------------|-------------------------------------|--------------------------|--------------------------|--------------------------|------|
| Transport  | A/D coefficient<br>Henry's constant | log Kow                  | Evaporation rate         | Method                   | Note |
| Soil-water | No information available            | No information available | No information available | No information available | -    |
| Water-air  | No information available            | No information available | No information available | No information available | -    |
| Soil-air   | No information available            | No information available | No information available | No information available | -    |

**12.5. Results of PBT and vPvB assessment**

|                          |  |  |  |  |  |  |
|--------------------------|--|--|--|--|--|--|
| No information available |  |  |  |  |  |  |
|--------------------------|--|--|--|--|--|--|

|               |  |                      |                  |
|---------------|--|----------------------|------------------|
| Trading name: | <b>GRAM LUGOL SOLUTION, STABILIZED</b> |                      |                  |
| Product code: | GLS-OT-X**                             | Date of compilation: | 14 November 2022 |
|               |  | Version:             | 5                |

|  |   |
|--|---|
| 12.6.                                      | Endocrine disrupting properties   |
|  | No known endocrine disrupting properties that affect the environment.   |
| 12.7.                                      | Other adverse effects   |
|  | No adverse effects are expected.  |
| <b>SECTION 13. Disposal considerations</b> |   |
| 13.1.                                      | Waste treatment methods   |
| 13.1.1.                                    | Product/Packaging disposal:   |
|  | Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.  |
| 13.1.2.                                    | Waste codes/waste designations according to Law:  |
|  | No information available  |
| 13.1.3.                                    | Waste treatment – relevant information:   |
|  | No information available  |
| 13.1.4.                                    | Sewage disposal – relevant information:   |
|  | Waste must not be disposed of into the sewage system.   |
| 13.1.5.                                    | Other disposal recommendations:   |
|  | Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur. |
| 13.1.6.                                    | Relevant Community provisions:  |
|  | -   |
| <b>SECTION 14. Transport information</b>   |   |
|  | Transporting/shipment by road (ADR)   |
| UN number:                                 | Not subject to transport regulations.   |
| UN proper shipping name:                   | -   |
| Transport hazard class(es):                | -   |

|               |  |                      |                  |
|---------------|--|----------------------|------------------|
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|               |  | Version:             | 5                |

|                               |   |
|-------------------------------|---|
| Packing group:                | - |
| Environmentally hazardous:    | - |
| Special precautions for user: | - |

Transporting/shipment by rail (RID)

|                               |                                       |
|-------------------------------|---------------------------------------|
| UN number:                    | Not subject to transport regulations. |
| UN proper shipping name:      | -                                     |
| Transport hazard class(es):   | -                                     |
| Packing group:                | -                                     |
| Environmentally hazardous:    | -                                     |
| Special precautions for user: | -                                     |

Inland waterway transport (ADN)

|                               |                                       |
|-------------------------------|---------------------------------------|
| UN number:                    | Not subject to transport regulations. |
| UN proper shipping name:      | -                                     |
| Transport hazard class(es):   | -                                     |
| Packing group:                | -                                     |
| Environmentally hazardous:    | -                                     |
| Special precautions for user: | -                                     |

Transporting/shipment by sea (IMDG)

|                               |                                       |
|-------------------------------|---------------------------------------|
| UN number:                    | Not subject to transport regulations. |
| UN proper shipping name:      | -                                     |
| Transport hazard class(es):   | -                                     |
| Packing group:                | -                                     |
| Environmentally hazardous:    | -                                     |
| Special precautions for user: | -                                     |

Transporting/shipment by air (ICAO-TI/IATA-DGR)

|                               |                                       |
|-------------------------------|---------------------------------------|
| UN number:                    | Not subject to transport regulations. |
| UN proper shipping name:      | -                                     |
| Transport hazard class(es):   | -                                     |
| Packing group:                | -                                     |
| Environmentally hazardous:    | -                                     |
| Special precautions for user: | -                                     |

|                      |   |
|----------------------|---|
| Further information: | The product is not subject to classification. |
|----------------------|---|

**SECTION 15. Regulatory information**

|               |  |                      |                  |          |   |
|---------------|--|----------------------|------------------|----------|---|
| Trading name: | <b>GRAM LUGOL SOLUTION, STABILIZED</b> |                      |                  |          |   |
| Product code: | GLS-OT-X**                             | Date of compilation: | 14 November 2022 | Version: | 5 |

|  |  |
|--|--|
| <b>15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture</b>  |  |
| EU regulations   |  |
| Authorization and/or restrictions of use   |  |
| Authorizations:  | -  |
| Restrictions:  | -  |
| Other EU regulations:  | <p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p> |
| Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline) |  |
| National legislation:  | <p>Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act</p>   |
| <b>15.2. Chemical safety assessment</b>  |  |
| None   |  |

|                                      |   |
|--------------------------------------|---|
| <b>SECTION 16. Other information</b> |   |
| 16.1. Indication of changes:         | - |

|               |  |                      |                  |          |   |
|---------------|--|----------------------|------------------|----------|---|
| Trading name: | <b>GRAM LUGOL SOLUTION, STABILIZED</b> |                      |                  |          |   |
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|       |   |   |
|-------|---|---|
| 16.2. | Abbreviations and acronyms:   | <p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p> |
| 16.3. | Key literature references and source of data:   | -   |
| 16.4. | Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP) |   |
|       | Classification  | Classification procedure  |
|       | -   | -   |
| 16.5. | Relevant H statements (number and full text)  |   |
|       | H:  | -   |
| 16.6. | Training advice:  |   |
|       |   | -   |
| 16.7. | Further information:  | <p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>  |

|   |
|---|
| <b>ANNEX: Exposure scenario resulting to Chemical safety assessment</b> |
| -   |