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|---------------|--------------------|----------------|-------------|
| Trading name: | HISTANOL 95 | | |
| Product code: | H95-X** | Revision date: | 13 May 2019 |
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

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| 1.1 | Product identifier | |
| | Trading name: | HISTANOL 95 |
| | Chemical name: | Ethyl alcohol |
| | Catalogue number: | H95-X** |
| 1.2 | Relevant identified uses of the substance or mixture and uses advised against | |
| | Uses: | For use in histocytology and cytology sample processing. |
| | 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 |
| | Telefax.: | +385 1 2404039 |
| | e-mail of competent person: | msds@biognost.hr |
| | 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*: |
| | Flam. Liq. 2 | H225 |
| 2.1.2. | Additional information | |
| | - | |
| *For full text of Hazard- and EU Hazard-statements: see SECTION 16 | | |
| 2.2 | Label elements | |
| | Product identification: | HISTANOL 95 |
| | Identification number: | - |
| | Authorization number: | - |

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| Hazard pictograms: |  |
| | GHS02 |
| Signal word: | Danger |
| Hazard statements: | H225 Highly flammable liquid and vapor. |
| Precautionary statements: | P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. |
| Supplemental hazard information (EU): | - |
| 2.3 | Other hazards |
| | - |

| SECTION 3. Composition/information on ingredients | | | | |
|---|-----------------------|-----------------------------|---------------------|--|
| CAS/EC/ Index number | REACH Registration No | Weight % content (or range) | Identification name | Classification according to Regulation (EC) No 1272/2008 (CLP) |
| 64-17-5/ 200-578-6/ 603-002-00-5 | 01-2119457610-43-xxxx | ~ 95% | ethanol | Flam. Liq. 2; H225 |

| SECTION 4. First aid measures | |
|-------------------------------|---|
| 4.1 | Description of first aid measures |
| General notes: | If the suggested first aid measures do not prove sufficient, seek medical attention. |
| Following inhalation: | Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen. |
| Following skin contact: | Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain. |
| Following eye contact: | Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist. |

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| | Following ingestion: | Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital. |
| | Self-protection of the first aider: | - |
| 4.2 | Most important symptoms and effects, both acute and delayed | |
| | Following inhalation: | Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea. |
| | Following skin contact: | Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking. |
| | Following eye contact: | Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain. |
| | Following ingestion: | Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting. |
| 4.3 | Indication of any immediate medical attention and special treatment needed | |
| | - | |

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| SECTION 5. Firefighting measures | | |
| 5.1 | Extinguishing media | |
| | Suitable extinguishing media: | Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam |
| | Unsuitable extinguishing media: | Water with full jet |
| 5.2 | Special hazards arising from the substance or mixture | |
| | Hazardous combustion products: | Formation of toxic gases is possible during heating or in case of fire. |
| 5.3 | Advice for firefighters | |
| | Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. | |
| 5.4 | Additional information | |
| | Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media. | |

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| SECTION 6. Accidental release measures | | |
| 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. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources. |

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| | Emergency procedures: | Mark the area using proper signs. |
| 6.1.2. | For emergency responders: | |
| | Use protective equipment; in case of inadequate ventilation use adequate airways 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 protective barrier or barriers made of similar materials. |
| 6.3.2. | Cleaning up: | Where possible, the substance can be absorbed by using absorbing material. 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: | Secure proper ventilation. Do not use incompatible materials (see Section 10). |
| 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. | |

| SECTION 7. Handling and storage | | |
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| 7.1 | Precautions for safe handling | |
| 7.1.1. | Protection measures | |
| | Measures to prevent fire: | Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. 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: | Protect against electrostatic charges. |
| 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 at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight. |

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| 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 10). | | |
| 7.3 Specific end use(s) | | | |
| 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 ³ | |
| Ethanol | 64-17-5 | 1000/- | 1900/- | - |

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| 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 | - | - | - | 950 mg/m ³ (ethanol) |
| Dermal | - | - | - | 343 mg/kg (ethanol) |

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

| Route of exposure: | Acute effect local | Acute effect systemic | Chronic effect local | Chronic effect systemic |
|--------------------|--------------------|-----------------------|----------------------|---------------------------------|
| Oral | - | - | - | - |
| Inhalation | - | - | - | 114 mg/m ³ (ethanol) |
| Dermal | - | - | - | 206 mg/kg (ethanol) |

PNEC

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| Environmental protection target | PNEC |
|------------------------------------|--------------------------|
| Fresh water | 0.96 mg/l (ethanol) |
| Freshwater sediments | 3.6 mg/kg (ethanol) |
| Marine water | 0.79 mg/l (ethanol) |
| Marine sediments | no information available |
| Food chain | no information available |
| Microorganisms in sewage treatment | no information available |
| Soil (agricultural) | 0.63 mg/kg (ethanol) |
| Air | no information available |

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| 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: | In accordance with Section 7. |
| | 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. Secure stations for rinsing eyes and showering. |
| 8.2.2. | Personal protection equipment | |
| 8.2.2.1. | Eye and face protection: | Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air. |
| 8.2.2.2. | Skin protection | |
| | Hand protection: | The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min |
| | Other skin protection: | During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material. |

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| 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 |
| | Colour: | colourless | No information available |
| | Odour: | alcohol like | No information available |
| | Odor threshold: | No information available | No information available |
| | pH: | No information available | No information available |
| | Melting point / freezing point; | -114.5°C | No information available |
| | Initial boiling point and boiling range: | 78 °C | No information available |
| | Flash point: | 13 °C | No information available |
| | Evaporation rate: | No information available | No information available |
| | Flammability (solid, gas): | No information available | No information available |
| | Upper/lower flammability or explosive limits: | lower: 3.5 Vol % upper: 15 Vol % | No information available |
| | Vapour pressure: | 59 hPa | No information available |
| | Vapour density: | No information available | No information available |
| | Relative density: | 0.711 – 0.87778 (20°C) | No information available |
| | Bulk density: | No information available | No information available |
| | Solubility(ies): | 1 g/l (20°C) | No information available |
| | Partition coefficient: n-octanol/water (log Kow): | No information available | No information available |

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| Auto-ignition temperature: | Product is not selfigniting | No information available |
| Decomposition temperature: | No information available | No information available |
| Viscosity: | 1.2 mPas (dynamic at 20°C) | No information available |
| Explosive properties: | Product is not explosive. However, formation of explosive air/vapour mixtures are possible. | No information available |
| Oxidising properties: | No information available | No information available |
| 9.2 Other information | | |
| Ignition temperature: 425 °C | | |

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| 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 (room temperature). |
| 10.3 | Possibility of hazardous reactions: | No dangerous reactions known. |
| 10.4 | Conditions to avoid: | Avoid heat, sparks, open flames and other ignition sources. |
| 10.5 | Incompatible materials: | No further relevant information available. |
| 10.6 | Hazardous decomposition products: | No dangerous decomposition products known. |

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| SECTION 11. Toxicological information | | | | | |
| 11.1 Information on toxicological effects | | | | | |
| Acute toxicity: | | | | | |
| Route of exposure: | Method | Species | Dose LD ₅₀ /LC ₅₀ or ATE _{mix} | Exposure time | Results |
| Oral: | - | rat (ethanol) | LD ₅₀ | - | 7.060 mg/kg |
| Dermal: | - | - | - | - | - |
| Inhalation: | - | rat (ethanol) | LC ₅₀ | 4 h | 20.000 mg/l |
| Specific target organ toxicity – single exposure (STOT SE): | | | | | |
| | Specific effects | | Target organ | | Note |
| Oral: | No information available | | No information available | | - |
| Dermal: | No information available | | No information available | | - |
| Inhalation: | No information available | | No information available | | - |
| Aspiration hazard: | | | | | |
| | | | No information available. | | |

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| Irritation and corrosion | | | | | | |
|--|---------------------------|--------------------------|--------------------------|--------------------------|--------------------------|------|
| | Exposure time | Species | Evaluation | Method | Note | |
| Skin corrosion/irritation: | - | - | - | - | - | - |
| Serious eye damage/irritation | - | - | - | - | - | - |
| Sensitization | | | | | | |
| Skin sensitization: | No information available. | | | | | |
| Respiratory sensitization: | No information available. | | | | | |
| Symptoms related to the physical, chemical and toxicological characteristics | | | | | | |
| Oral exposure: | No information available. | | | | | |
| Dermal exposure: | No information available. | | | | | |
| Inhalation exposure: | No information available. | | | | | |
| Eye exposure: | No information available. | | | | | |
| 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 | - |

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|--------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| 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 | - |

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| 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 | - |
| 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 | - |

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| CMR effects (carcinogenicity; mutagenicity; reproductive toxicity) | | | | | | |
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|--------------------------------|---|--|--|--|--|--|
| Carcinogenicity: | Based on available data, the classification criteria are not met. | | | | | |
| Mutagenicity <i>in vitro</i> : | Based on available data, the classification criteria are not met. | | | | | |
| Genotoxicity: | Based on available data, the classification criteria are not met. | | | | | |
| Mutagenicity <i>in vivo</i> : | Based on available data, the classification criteria are not met. | | | | | |
| Germ cell mutagenicity: | Based on available data, the classification criteria are not met. | | | | | |
| Reproductive toxicity: | Based on available data, the classification criteria are not met. | | | | | |

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| Summary of evaluation of the CMR properties: | Based on available data, the classification criteria are not met. | | | | | |
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| 11.2 | Practical experiences: | | | | | |
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|------------------------------|--------------------------|--|--|--|--|--|
| Classification observations: | No information available | | | | | |
|------------------------------|--------------------------|--|--|--|--|--|

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|---------------------|--------------------------|--|--|--|--|--|
| Other observations: | No information available | | | | | |
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| 11.3 | General notes: | | | | | |
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SECTION 12. Ecological information

12.1 Toxicity

| Acute (short-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
|-----------------------------|------------------|---------------|--------------------------|--------------------------|--------------------------|------|
| Fish | LC ₅₀ | 96 hours | No information available | No information available | No information available | - |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | - |
| Algae/aquatic plants | IC ₅₀ | 4 days | No information available | No information available | No information available | - |
| Other organisms | - | - | - | - | - | - |

| Chronic (long-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
|------------------------------|------------------|---------------|--------------------------|--------------------------|--------------------------|------|
| Fish | LC ₅₀ | 96 hours | No information available | No information available | No information available | - |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | - |
| Algae/aquatic plants | IC ₅₀ | 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 |
|---------------|-------------|--------|------------|------|
|---------------|-------------|--------|------------|------|

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| 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 |
| - | - | - | - | - | - | - |
| | | | | | | |

Bioconcentration factor (BCF)

| Value | Species | Method | Evaluation | Note |
|--------------------------|--------------------------|--------------------------|--------------------------|------|
| 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 ₅₀ | No information available | No information available | No information available | No information available | - |
| Chronic toxicity on crustacea (<i>Daphnia</i>) | EC ₅₀ | 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 | - | | |

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

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| 12.5 | Results of PBT and vPvB assessment |
| | Not applicable. |

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| 12.6 | Other adverse effects |
| | No further relevant information available. |

SECTION 13. Disposal considerations

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|-------------|--------------------------------|
| 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: |
| | Packaging that contains residual hazardous substances or is contaminated with hazardous substances |

| | |
|----------------|--|
| 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. |

| | | | | |
|---------------|--------------------|----------------|-------------|----------|
| Trading name: | HISTANOL 95 | | | |
| Product code: | H95-X** | Revision date: | 13 May 2019 | Version: |

| | |
|---------|--|
| 13.1.6. | Relevant Community provisions: |
| | Disposal must be made according to official regulations. |

SECTION 14 TRANSPORT INFORMATION

| | |
|---|---|
| | Transporting/shipment by road (ADR) |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| | Transporting/shipment by rail (RID) |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| | Inland waterway transport (ADN) |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| | Transporting/shipment by sea (IMDG) |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code: | - |
| | Transporting/shipment by air (ICAO-TI/IATA-DGR) |
| UN number: | 1170 |

| | | | | |
|---------------|--------------------|----------------|-------------|----------|
| Trading name: | HISTANOL 95 | | | |
| Product code: | H95-X** | Revision date: | 13 May 2019 | Version: |

| | |
|-------------------------------|------------------|
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| Further information: | - |

| SECTION 15. Regulatory information | |
|------------------------------------|--|
| 15.1 | Safety, health and environmental regulations/legislation specific for the substance or mixture |
| | EU regulations |
| | Authorization and/or restrictions of use |
| | Authorizations: - |
| | Restrictions: - |
| | Other EU regulations: EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives |
| | Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline) |
| | National legislation: 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 |
| 15.2 | Chemical safety assessment |
| | None |

| SECTION 16. Other information | |
|-------------------------------|--------------------------|
| 16.1 | Indication of changes: - |

| | | | |
|---------------|--------------------|----------------|-------------|
| Trading name: | HISTANOL 95 | | |
| Product code: | H95-X** | Revision date: | 13 May 2019 |
| | | Version: | |

| | | | |
|-------|---|--|--|
| 16.2 | Abbreviations and acronyms: | PBT | Stable, bioaccumulative and toxic |
| | | vPvB | Strongly stable and strongly bioaccumulative. |
| | | LD ₅₀ | Lethal dose, 50% |
| | | LC ₅₀ | Lethal concentration, 50% |
| | | TCOJ | Specific target organ toxicity - single exposure |
| 16.3. | Key literature references and source of data: | Manufacturer's MSDS file. | |
| 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: | H225 | Highly flammable liquid and vapor. |
| 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> | |

| |
|---|
| ANNEX: Exposure scenario resulting to chemical safety assessment |
| - |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
| Trading name: | HEMATOXYLIN HP, PAP 1A | | | | |
| Product code: | HEMHP-OT-X** | Revision date: | 04.06.2019. | Version: | 5 |


SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

| | |
|--|---|
| 1.1. Product identifier | |
| Trading name: | HEMATOXYLIN HP, PAP 1A |
| Chemical name: | - |
| Catalogue number: | HEMHP-OT-X** |
| 1.2. Relevant identified uses of the substance or mixture and uses advised against | |
| Uses: | Modified hematoxylin acc. to Harris for nuclear staining acc. to Papanicolaou. |
| 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: | msds@biognost.hr |
| National contact: | - |
| 1.4. Emergency telephone number | |
| National Protection and Rescue Directorate: | 112 |
| Medical information: | +385 1 2348 342 |
| Other information: | - |

SECTION 2 HAZARDS INFORMATION

| | |
|--|------------------------|
| 2.1. Classification of the substance or mixture | |
| 2.1.1. Classification (REGULATION (EC) No. 1272/2008 (CLP)) | |
| Hazard class and category code: | Hazard statements*: |
| Eye Irr. 2 | H319 |
| 2.1.2. Additional information | |
| - | |
| *For full text of Hazard- and EU Hazard-statements: see Section 16 | |
| 2.2. Classification according to EC Directive Nr. 1272/2008 CLP) | |
| Product identification: | HEMATOXYLIN HP, PAP 1A |
| Identification number: | - |
| Authorization no.: | - |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
| Trading name: | HEMATOXYLIN HP, PAP 1A | | | | |
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| | |
|---------------------------|--|
| Hazard pictograms: |  |
| | GHS07 |
| Signal word: | Warning |
| Hazard statements: | H319 Causes serious eye irritation. |
| Precautionary statements: | P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. |
| Further information: | - |
| 2.3. Other hazards | |
| - | |

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) |
|---|---------------------------|--------------------------------|-------------------------------------|---|
| 107-21-1/ 203-473-3/ 603-027-00-1 | 01-2119456816- 28-xxxx | ≤ 15% | ethylene glycol | Acute Tox. 4, H302 |
| 17927-65-0/ 605-852-2/ - | - | < 10% | aluminum sulfate octadecahydrate | Eye Dam. 1; H318 |

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. |

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|---------------|-------------------------------|----------------|-------------|----------|---|
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| | | |
|-------------|---|--|
| | 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: | Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea. |
| | Following skin contact: | Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin. |
| | Following eye contact: | Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation. |
| | Following ingestion: | Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation. |
| 4.3. | Indication of any immediate medical attention and special treatment needed | |
| | - | |

| | | |
|--|---|---|
| SECTION 5 FIREFIGHTING MEASURES | | |
| 5.1. | Extinguishing media | |
| | Suitable extinguishing media: | Small fire - water spray, dry powder, CO ₂ 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. Cool closed containers exposed to fire with water spray or vapor. | |
| 5.4. | Additional information | |
| | Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media. | |

| | | |
|--|--|--|
| SECTION 6 ACCIDENTAL RELEASE MEASURES | | |
| 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). |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
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| | | |
|--------|---|---|
| | 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. | Bunding, covering of drains; capping procedures: | Sand or clay barriers. |
| 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 | |
| | - | |

SECTION 7 HANDLING AN STORAGE

| | | |
|--------|--|---|
| 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. |

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|---------------|-------------------------------|----------------|-------------|----------|---|
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| | |
|---|---|
| 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) | |
| 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 ³ | |
| Ethylene glycol | 107-21-1 | 20/40 | 52/104 | 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 | - | - | 35 mg/ kg (ethylene glycol) | - |
| Dermal | - | - | - | 106 mg/kg (ethylene glycol) |

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

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

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
| Trading name: | HEMATOXYLIN HP, PAP 1A | | | | |
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| | | | | |
|------------|---|---|------------------------------|-------------------------------|
| Inhalation | - | - | 7 mg/kg (ethylene glycol) | - |
| Dermal | - | - | - | 53 mg/kg (ethylene glycol) |

| PNEC | |
|------------------------------------|------------------------------|
| Environmental protection target | PNEC |
| Fresh water | 10 mg/l (ethylene glycol) |
| Freshwater sediments | 37 mg/kg (ethylene glycol) |
| Marine water | 1 mg/l (ethylene glycol) |
| Marine sediments | 3.7 mg/kg (ethylene glycol) |
| Food chain | No information available |
| Microorganisms in sewage treatment | 199.5 mg/l (ethylene glycol) |
| Soil (agricultural) | 1.53 mg/kg (ethylene glycol) |
| Air | No information available |

| | | |
|----------|--|--|
| 8.2. | Exposure controls | |
| 8.2.1. | Engineering measures | |
| | 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. Glove material: nitrile rubber Glove thickness: ≥0.50 mm 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). |

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|---------------|-------------------------------|----------------|-------------|----------|---|
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| | | |
|----------|---|--|
| 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

| | | | |
|------|---|--------------------------|--------------------------|
| 9.1. | Information on basic physical and chemical properties | | |
| | | Value | Method |
| | Physical state: | liquid | No information available |
| | Color: | red-purple | No information available |
| | Odor: | No information available | No information available |
| | Odor threshold: | No information available | No information available |
| | pH: | 2.3 - 2.5 | No information available |
| | Melting point / freezing point: | No information available | No information available |
| | Initial boiling point and boiling range: | No information available | No information available |
| | Flash point: | No information available | No information available |
| | Evaporation rate: | No information available | No information available |
| | Flammability (solid, gas): | No information available | No information available |
| | Upper/lower flammability or explosive limits: | No information available | No information available |
| | Vapor pressure: | No information available | No information available |
| | Vapor density: | No information available | No information available |
| | Relative density: | No information available | No information available |
| | Bulk density: | No information available | No information available |
| | Solubility(ies): | Soluble in water (20 °C) | No information available |
| | Partition coefficient: n-octanol/water (log Kow): | No information available | No information available |
| | Auto-ignition temperature: | No information available | No information available |
| | Decomposition temperature: | No information available | No information available |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
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| | | |
|------------------------|--------------------------|--------------------------|
| Viscosity: | No information available | No information available |
| Explosive properties: | No information available | No information available |
| Oxidising properties: | 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: | With strong oxidants, sodium-hydroxide, sulfuric acid, aluminum. | |
| 10.4. Conditions to avoid: | Sources of heat, sparks, and ignition. | |
| 10.5. Incompatible materials: | Aluminum. | |
| 10.6. Hazardous decomposition products: | No information available. | |

| SECTION 11 TOXICOLOGICAL INFORMATION | | | | | |
|---|--------------------------|--------------------------|---|---------------|----------------------------------|
| 11.1. Information on toxicological effects | | | | | |
| Acute toxicity: | | | | | |
| Route of exposure: | Method | Species | Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture} | Exposure time | Results |
| Oral exposure: | No information available | rat | LD ₅₀ | - | 7.712 mg/kg (ethylene glycol) |
| Dermal exposure: | No information available | rabbit | LD ₅₀ | - | >3.500mg/kg (ethylene glycol) |
| Inhalation exposure: | No information available | - | LC ₅₀ | - | - |
| 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 | - | | |
| Respiratory irritation: No information available | | | | | |
| Irritation and corrosion | | | | | |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
| Trading name: | HEMATOXYLIN HP, PAP 1A | | | | |
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| | Exposure time | Species | Evaluation | Method | Note |
|------------------|---------------|---------|------------|--------|-------------------------------------|
| Skin irritation: | - | rabbit | - | - | Slight irritation (ethylene glycol) |
| Eye irritation: | 24 h | rabbit | - | - | Slight irritation (ethylene glycol) |

Sensitization

| | |
|----------------------|--------------------------|
| Dermal exposure: | No information available |
| Inhalation exposure: | No information available |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|----------------------|--|
| Oral exposure: | Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation. |
| Dermal exposure: | Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin. |
| Inhalation exposure: | Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea. |
| Eye exposure: | Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation. |

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 | - |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
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| | | | | | | |
|-----------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| 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 | - |
| 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. Practical experiences: | |
| Remarks relevant for classification: | No information available |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
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| | |
|----------------------|--------------------------|
| Other remarks: | No information available |
| 11.3. General notes: | - |

SECTION 12 ECOLOGICAL INFORMATION:

12.1. Toxicity

| Acute toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
|----------------------|------------------|---------------|--------------------------|--------------------------|-------------------------------------|------|
| Fish | LC ₅₀ | 96 hours | Fish | No information available | 72.860 mg/l (ethylene glycol) | - |
| Crustacea: | EC ₅₀ | 48 hours | water flea | No information available | >100 mg/l (ethylene glycol) | - |
| Algae/aquatic plants | IC ₅₀ | 8 days | algae | No information available | 6.500-13.000 mg/l (ethylene glycol) | - |
| Microorganisms | LC ₅₀ | 72 hours | - | - | - | - |
| Chronic toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
| Fish | LC ₅₀ | 96 hours | No information available | No information available | No information available | - |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | - |
| Algae/aquatic plants | IC ₅₀ | 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 | - |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
| Trading name: | HEMATOXYLIN HP, PAP 1A | | | | |
| Product code: | HEMHP-OT-X** | Revision date: | 04.06.2019. | Version: | 5 |

| 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

| Partition coefficient: n-octanol/water (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 |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 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 ₅₀ | No information available | No information available | No information available | No information available | - |
| Chronic toxicity on crustacea (<i>Daphnia</i>) | EC ₅₀ | No information available | No information available | No information available | No information available | - |

12.4. Mobility in soil

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

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

Adsorption / desorption

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

12.5. Results of PBT and vPvB assessment

No information available

12.6. Other adverse effects

No information available

SECTION 13 DISPOSAL CONSIDERATIONS

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.

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
| Trading name: | HEMATOXYLIN HP, PAP 1A | | | | |
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| | |
|---------|---|
| 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: |
| | - |

SECTION 14 TRANSPORT INFORMATION

| | |
|-------------------------------------|---------------------------------------|
| Transporting/shipment by road (ADR) | |
| 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 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: | - |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
| Trading name: | HEMATOXYLIN HP, PAP 1A | | | | |
| Product code: | HEMHP-OT-X** | Revision date: | 04.06.2019. | Version: | 5 |

| | |
|--|---------------------------------------|
| 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 | |
|--|--|
| 15.1. | Safety, health and environmental regulations/legislation specific for the substance or mixture |
| | EU regulations |
| | Authorization and/or restrictions of use |
| | Authorizations: - |
| | Restrictions: - |
| | Other EU regulations: EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/200 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives |
| | Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline) |
| | National legislation: 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 |
| 15.2. | Chemical safety assessment |
| | None |

| | | | | | |
|---------------|-------------------------------|----------------|-------------|----------|---|
| Trading name: | HEMATOXYLIN HP, PAP 1A | | | | |
| Product code: | HEMHP-OT-X** | Revision date: | 04.06.2019. | Version: | 5 |

| SECTION 16 Other information | | |
|-------------------------------------|---|---|
| 16.1. | Indication of changes: | - |
| 16.2. | Abbreviations and acronyms: | PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD ₅₀ Lethal dose, 50% LC ₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity - single exposure |
| 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: 302 318 319 | Harmful if swallowed. Causes serious eye damage. Causes serious eye irritation. |
| 16.6. | Training advice: | - |
| 16.7. | Further information: | ** "X" in the product code marks different volumes (different packagings of the product) 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. |

| |
|--|
| ANNEX: |
| EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT |
| - |

| | | | | | |
|---------------|-----------------------|----------------------|--------------|----------|---|
| Trading name: | BLUING REAGENT | | | | |
| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 | Version: | 4 |

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

| | |
|---|---|
| 1.1. Product identifier | |
| Trading name: | BLUING REAGENT |
| Chemical name: | - |
| Catalogue number: | BR-OT-X** |
| 1.2. Relevant identified uses of the substance or mixture and uses advised against | |
| Uses: | Reagent for conversion of red hematoxylin-stained nuclei to blue. |
| 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: | msds@biognost.hr |
| National contact: | - |
| 1.4. Emergency telephone number | |
| National Protection and Rescue Directorate: | 112 |
| Medical information: | +385 1 2348 342 |
| Other information: | - |

SECTION 2 HAZARDS INFORMATION

| | |
|---|---------------------|
| 2.1. Classification of the substance or mixture | |
| 2.1.1. Classification (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. Classification according to EC Directive Nr. 1272/2008 CLP) | |
| Product identification: | BLUING REAGENT |
| Identification number: | - |
| Authorization no.: | - |
| Hazard pictograms: | - |
| Signal word: | - |

| | | | | |
|---------------|-----------------------|----------------------|--------------|------------|
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| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 | Version: 4 |

| | |
|---------------------------|---|
| Hazard statements: | - |
| Precautionary statements: | - |
| Further information: | - |
| 2.3. Other hazards | |
| - | |

| 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: | Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea. |
| Following skin contact: | Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin. |
| Following eye contact: | Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation. |

| | | | |
|---------------|-----------------------|----------------------|--------------|
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| | | |
|------|--|--|
| | Following ingestion: | Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation. |
| 4.3. | Indication of any immediate medical attention and special treatment needed | |
| | - | |

| SECTION 5 FIREFIGHTING MEASURES | | |
|--|--|---|
| 5.1. | Extinguishing media | |
| | Suitable extinguishing media: | Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam |
| | Unsuitable extinguishing media: | No information available |
| 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. Cool closed containers exposed to fire with water spray or vapor. | |
| 5.4. | Additional information | |
| | Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media. | |

| SECTION 6 ACCIDENTAL RELEASE MEASURES | | |
|--|---|--|
| 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 | |
| | | - |

| SECTION 7 HANDLING AN STORAGE | |
|--------------------------------------|--|
| 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) |
| | Recommendations: - |
| | Industrial sector specific solutions: - |

| | | | | |
|---------------|-----------------------|----------------------|--------------|------------|
| Trading name: | BLUING REAGENT | | | |
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| 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 ³ | |
| - | - | - | - | 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 | | |
| Air | | No information available | | |
| 8.2. Exposure controls | | | | |

| | | | |
|---------------|-----------------------|----------------------|--------------|
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| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 |
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| | | |
|----------|--|--|
| 8.2.1. | Engineering measures | |
| | 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. Glove material: nitrile rubber Glove thickness: ≥0.50 mm 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 | | | |
|---|---|------------|--------------------------|
| 9.1. | Information on basic physical and chemical properties | | |
| | | Value | Method |
| | Physical state: | liquid | No information available |
| | Color: | colourless | No information available |

| | | | |
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| | | |
|---|--------------------------|--------------------------|
| Odor: | no odor | No information available |
| Odor threshold: | No information available | No information available |
| pH: | >8.0 | No information available |
| Melting point / freezing point: | No information available | No information available |
| Initial boiling point and boiling range: | No information available | No information available |
| Flash point: | No information available | No information available |
| Evaporation rate: | No information available | No information available |
| Flammability (solid, gas): | No information available | No information available |
| Upper/lower flammability or explosive limits: | No information available | No information available |
| Vapor pressure: | No information available | No information available |
| Vapor density: | No information available | No information available |
| Relative density: | No information available | No information available |
| Bulk density: | No information available | No information available |
| Solubility(ies): | Soluble in water (20 °C) | No information available |
| Partition coefficient: n-octanol/water (log Kow): | No information available | No information available |
| Auto-ignition temperature: | No information available | No information available |
| Decomposition temperature: | No information available | No information available |
| Viscosity: | No information available | No information available |
| Explosive properties: | No information available | No information available |
| Oxidising properties: | 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 | |
|---|--------------------------------------|
| 11.1. | Information on toxicological effects |
| | Acute toxicity: |

| | | | | | |
|---------------|-----------------------|----------------------|--------------|----------|---|
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| Route of exposure: | Method | Species | Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture} | Exposure time | Results |
|----------------------|--------------------------|---------|---|---------------|---------|
| Oral exposure: | No information available | - | LD ₅₀ | - | - |
| Dermal exposure: | No information available | - | LD ₅₀ | - | - |
| Inhalation exposure: | No information available | - | LC ₅₀ | - | - |

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 | - |

Respiratory irritation: No information available

Irritation and corrosion

| | Exposure time | Species | Evaluation | Method | Note |
|------------------|---------------|---------|------------|--------|------|
| Skin irritation: | - | rabbit | - | - | - |
| Eye irritation: | - | rabbit | - | - | - |

Sensitization

| | |
|----------------------|--------------------------|
| Dermal exposure: | No information available |
| Inhalation exposure: | No information available |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|----------------------|---|
| Oral exposure: | Swallowing may cause discomfort in abdomen and abdominal pains. |
| Dermal exposure: | Allergic persons may display irritation. |
| Inhalation exposure: | Allergic persons may display irritation after prolonged or repeated exposure. |
| Eye exposure: | May cause irritation. |

Repeated dose toxicity (subacute, subchronic, chronic)

| | Dose | Exposure time | Species | Method | Evaluation | Note |
|--|------|---------------|---------|--------|------------|------|
|--|------|---------------|---------|--------|------------|------|

| | | | | | | |
|---------------|-----------------------|----------------------|--------------|----------|---|--|
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| | | | | | | |
|-----------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| 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 | - |
| 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)

| | | | | | |
|---------------|-----------------------|----------------------|--------------|----------|---|
| Trading name: | BLUING REAGENT | | | | |
| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 | Version: | 4 |

| | |
|--------------------------------|---|
| 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. Practical experiences: | |
| Remarks relevant for classification: | No information available |
| Other remarks: | No information available |

| | |
|-----------------------------|--|
| 11.3. General notes: | |
| - | |

SECTION 12 ECOLOGICAL INFORMATION:

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

| | | | | | |
|---------------|-----------------------|----------------------|--------------|----------|---|
| Trading name: | BLUING REAGENT | | | | |
| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 | Version: | 4 |

| | | | | | |
|-----------------|---|---|---|---|---|
| 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

Partition coefficient: n-octanol/water (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 |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 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 ₅₀ | No information | No information | No information | No information available | - |

| | | | | | | |
|---------------|-----------------------|----------------------|--------------|----------|---|--|
| Trading name: | BLUING REAGENT | | | | | |
| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 | Version: | 4 | |

| | | | | | | |
|--|------------------|---------------------------------------|---------------------------------------|---------------------------------------|--------------------------|---|
| Chronic toxicity on crustacea (<i>Daphnia</i>) | EC ₅₀ | available No information available | available No information available | 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 Henry's constant | | log Kow | Evaporation rate | Method | Note |
| Soil-water | No information available | 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 | No information available | - |
| Soil-air | No information available | No information available | No information available | No information available | No information available | - |

12.5. Results of PBT and vPvB assessment

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

12.6. Other adverse effects

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

SECTION 13 DISPOSAL CONSIDERATIONS

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. | | | | | | |
|--|--|--|--|--|--|--|

| | | | |
|---------------|-----------------------|----------------------|--------------|
| Trading name: | BLUING REAGENT | | |
| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 |
| | | Version: | 4 |

| | |
|---------|---|
| 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: |
| | - |

SECTION 14 TRANSPORT INFORMATION

| | |
|-------------------------------------|---------------------------------------|
| Transporting/shipment by road (ADR) | |
| 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 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): | - |

| | | | |
|---------------|-----------------------|----------------------|--------------|
| Trading name: | BLUING REAGENT | | |
| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 |
| | | Version: | 4 |

| | |
|---|---------------------------------------|
| 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: | |
| | - |

| SECTION 15 REGULATORY INFORMATION | |
|--|--|
| 15.1. | Safety, health and environmental regulations/legislation specific for the substance or mixture |
| | EU regulations |
| | Authorization and/or restrictions of use |
| | Authorizations: - |
| | Restrictions: - |

| | | | | |
|---------------|-----------------------|----------------------|--------------|------------|
| Trading name: | BLUING REAGENT | | | |
| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 | Version: 4 |

| | |
|--|--|
| Other EU regulations: | <p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</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> |
| 15.2. Chemical safety assessment | |
| | None |

| SECTION 16 Other information | | | | | | | | | | | |
|---|--|-----|-----------------------------------|------|---|------------------|------------------|------------------|---------------------------|---------|--|
| 16.1. Indication of changes: | - | | | | | | | | | | |
| 16.2. Abbreviations and acronyms: | <table> <tr> <td>PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td>LD₅₀</td> <td>Lethal dose, 50%</td> </tr> <tr> <td>LC₅₀</td> <td>Lethal concentration, 50%</td> </tr> <tr> <td>STOT-SE</td> <td>Specific target organ toxicity - single exposure</td> </tr> </table> | PBT | Stable, bioaccumulative and toxic | vPvB | Strongly stable and strongly bioaccumulative. | LD ₅₀ | Lethal dose, 50% | LC ₅₀ | Lethal concentration, 50% | STOT-SE | Specific target organ toxicity - single exposure |
| PBT | Stable, bioaccumulative and toxic | | | | | | | | | | |
| vPvB | Strongly stable and strongly bioaccumulative. | | | | | | | | | | |
| LD ₅₀ | Lethal dose, 50% | | | | | | | | | | |
| LC ₅₀ | Lethal concentration, 50% | | | | | | | | | | |
| STOT-SE | Specific target organ toxicity - single exposure | | | | | | | | | | |
| 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: | - | | | | | | | | | | |

| | | | | | |
|---------------|-----------------------|----------------------|--------------|----------|---|
| Trading name: | BLUING REAGENT | | | | |
| Product code: | BR-OT-X** | Date of compilation: | 04 June 2019 | Version: | 4 |

| | | |
|-------|----------------------|--|
| 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> |
|-------|----------------------|--|


| | |
|--|--|
| <p>ANNEX: EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT</p> | |
| - | |

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
| Trade name: | OG-6 REAGENT, PAP 2A | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: 2 |

| SECTION 1: Identification of the substance/mixture and of the company/undertaking | |
|--|---|
| 1.1. | Product identifier |
| | Trade name: OG-6 REAGENT, PAP 2A |
| | Chemical name: - |
| | Catalogue number: OG6-OT-X** |
| 1.2. | Relevant identified uses of the substance or mixture and uses advised against |
| | Uses: Cytoplasmic staining reagent acc. to Papanicolaou. |
| | 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 |
| | Telefax: +385 1 2404039 |
| | E-mail of competent person: msds@biognost.hr |
| | National contact: - |
| 1.4. | Emergency telephone numbers |
| | 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 statement*: |
| | Flam. Liq. 2 H225 |
| 2.1.2. | Additional information |
| | - |
| *For full text of Hazard- and EU Hazard-statements: see Section 16. | |
| 2.2. | Label elements |
| | Product identification: OG-6 REAGENT, PAP 2A |
| | Identification number: - |
| | Authorisation number: - |

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
| Trade name: | OG-6 REAGENT, PAP 2A | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: 2 |

| | |
|---------------------------------------|---|
| Hazard pictograms: |  |
| | GHS02 |
| Signal word: | Danger |
| Warning statement: | H225 Highly flammable liquid and vapor. |
| Precautionary statement: | P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. |
| Supplemental hazard information (EU): | - |
| 2.3. Other hazards | |
| - | |

| SECTION 3. Composition/information on ingredients | | | | |
|--|-----------------------|-----------------------------|---------------------|--|
| CAS/EC/ Index number | REACH Registration No | Weight % content (or range) | Identification name | Classification according to Regulation (EC) No 1272/2008 (CLP) |
| 64-17-5/ 200-578-6/ 603-002-00-5 | - | ≥ 60 | ethanol | Flam. Liq. 2; H225 |
| 107-21-1/ 203-473-3/ 603-027-00-1 | - | < 10 | ethylene glycol | Acute Tox. 4; H302 |

| SECTION 4. First aid measures | |
|--------------------------------------|---|
| 4.1. | Description of first aid measures |
| General notes: | If the suggested first aid measures do not prove sufficient, seek medical attention. |
| Following inhalation: | Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen. |
| Following skin contact: | Remove all contaminated clothes/footwear. Thoroughly wash with water for at least 15 minutes. |
| Following eye contact: | Rinse the eyes using mild jet of clean water for at least 20 minutes with the eyelids held wide open. |

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
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| | | |
|-------------|---|--|
| | Following swallowing: | Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital. |
| | Self-protection of the first aider | - |
| 4.2. | Most important symptoms and effects, both acute and delayed | |
| | Following inhalation: | Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea. |
| | Following skin contact: | Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking. |
| | Following eye contact: | Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain. |
| | Following swallowing: | Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting. |
| 4.3. | Indication of any immediate medical attention and special treatment needed | |
| | No information available | |

| | | |
|---|--|---|
| SECTION 5. Firefighting measures | | |
| 5.1. | Extinguishing media | |
| | Suitable extinguishing media: | Small fire - water spray, dry powder, alcohol-resistant foam, CO2 Large fire - water spray or alcohol-resistant foam |
| | Unsuitable extinguishing media: | Water with full jet |
| 5.2. | Special hazards arising from the substance or mixture | |
| | Hazardous byproducts of fire: | Incomplete combustion of the product. |
| 5.3. | Advice for firefighters | |
| | Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing). | |
| 5.4. | Additional information | |
| | Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media. | |

| | | |
|---|--|--|
| SECTION 6. Accidental release measures | | |
| 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). |

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
| Trade name: | OG-6 REAGENT, PAP 2A | | | |
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| | | |
|--------|---|--|
| | Accident prevention methods: | Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources. |
| | Emergency procedures: | Mark the area using proper signs. |
| 6.1.2. | For emergency responders: | |
| | Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing). | |
| 6.2. | Environmental precautions: | |
| | Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater. | |
| 6.3. | Methods and materials for containment and cleaning up | |
| 6.3.1. | Bundling, covering of drains; capping procedures: | Sand protective barrier or barriers made of similar materials |
| 6.3.2. | Cleaning up: | Sawdust, sand, mineral adsorbents |
| 6.3.3. | Other information: | Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112). Do not use incompatible materials (see Section 10). |
| 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. | |

| | | |
|--|--|---|
| SECTION 7. Handling and storage | | |
| 7.1. | Precautions for safe handling | |
| 7.1.1. | Protection measures | |
| | Measures to prevent fire: | Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. 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: | Protect against electrostatic charges. |
| 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 at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight. |

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
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| | | |
|---|--|--|
| 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 10). | |
| 7.3. Specific end use(s) | | |
| 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 ³ | |
| Ethanol | 64-17-5 | 1000/- | 1900/- | No information available |
| Ethylene glycol | 107-21-1 | 20/40 | 52/104 | No information available |

| | |
|------------|---|
| Substance: | - |
| EC No: | - |
| CAS No: | - |

DNEL

Industrial

| Route of exposure: | Acute effect local | Acute effect systemic | Chronic effect local | Chronic effect systemic |
|--------------------|--------------------|-----------------------|--------------------------------|--|
| Oral | - | - | - | - |
| Inhalation | - | - | 35 mg/ kg (ethylene glycol) | 950 mg/m ³ (ethanol) |
| Dermal | - | - | - | 343 mg/kg (ethanol) 106 mg/kg (ethylene glycol) |

| | |
|--|---|
| Critical physical parameters: solubility, flammability, corrosivity: | - |
|--|---|

Consumer

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

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
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| | | | | |
|------------|---|---|------------------------------|---|
| Inhalation | - | - | 7 mg/kg (ethylene glycol) | 950 mg/m ³ (ethanol) |
| Dermal | - | - | - | 343 mg/kg (ethanol) 53 mg/kg (ethylene glycol) |

| PNEC | |
|------------------------------------|--|
| Environmental protection target | PNEC |
| Fresh water | 0.96 mg/l (ethanol) 10 mg/l (ethylene glycol) |
| Freshwater sediments | 3.6 mg/kg (ethanol) 37 mg/kg (ethylene glycol) |
| Marine water | 0.79 mg/l (ethanol) 1 mg/kg (ethylene glycol) |
| Marine sediments | 3.7 mg/kg (ethylene glycol) |
| Food chain | no information available |
| Microorganisms in sewage treatment | no information available |
| Soil (agricultural) | 0.63 mg/kg (ethanol) 1.53 mg/kg (ethylene glycol) |
| Air | no information available |

| | |
|--|--|
| 8.2. Exposure controls | |
| 8.2.1. Appropriate engineering controls | |
| Substance/mixture related measures to prevent exposure during identified uses: | Do not eat, drink or smoke in the workspace. Use personal protective equipment. |
| 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: | See Section 7.2 |
| 8.2.2. Personal protection equipment | |
| 8.2.2.1. Eye and face protection: | Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air. |
| 8.2.2.2. Skin protection | |

| | | | | |
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| | | |
|----------|---|---|
| | Hand protection: | Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min |
| | Other skin protection: | During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material. |
| 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 | | | |
|--|---|--------------------------|--------------------------|
| 9.1. Information on basic physical and chemical properties | | | |
| | | Value | Method |
| | Physical state: | liquid | no information available |
| | Colour: | orange | no information available |
| | Odour: | ethanol like | no information available |
| | Odour threshold; | no information available | no information available |
| | pH: | 3.0-5.5 | no information available |
| | Melting point / freezing point; | no information available | no information available |
| | Initial boiling point and boiling range: | no information available | no information available |
| | Flash point: | 19 °C | no information available |
| | Evaporation rate: | no information available | no information available |
| | Flammability (solid, gas): | no information available | no information available |
| | Upper/lower flammability or explosive limits: | no information available | no information available |
| | Vapour pressure: | no information available | no information available |

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
| Trade name: | OG-6 REAGENT, PAP 2A | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: 2 |

| | | |
|---|--------------------------|--------------------------|
| Vapour density: | no information available | no information available |
| Relative density | no information available | no information available |
| Bulk density: | No information available | no information available |
| Solubility(ies): | no information available | no information available |
| Partition coefficient: n-octanol/water (log Kow): | no information available | no information available |
| Auto-ignition temperature: | no information available | no information available |
| Decomposition temperature: | no information available | no information available |
| Viscosity: | no information available | no information available |
| Explosive properties: | no information available | no information available |
| Oxidising properties: | no information available | no information available |
| 9.2. Other information | | |
| | - | |

| SECTION 10.: Stability and reactivity | | |
|--|---|--|
| 10.1. Reactivity: | The product is stable under normal working and storage conditions. | |
| 10.2. Chemical stability: | The product is chemically stable under standard ambient conditions of storing and using. | |
| 10.3. Possibility of hazardous reactions: | Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances. | |
| 10.4. Conditions to avoid: | Avoid heat, sparks, open flames and other ignition sources. | |
| 10.5. Incompatible materials: | Oxidants, acids, alkali metals. | |
| 10.6. Hazardous decomposition products: | Non-degradable if used in the described manner. | |

| SECTION 11. Toxicological information | | | | | |
|--|--------------------------|---------|---|---------------|--|
| 11.1. Information on toxicological effects | | | | | |
| Acute toxicity: | | | | | |
| Route of exposure: | Method | Species | Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture} | Exposure time | Results |
| Oral: | No information available | rat | LD ₅₀ | - | 7.060 mg/kg (ethanol) 7.712 mg/kg (ethylene glycol) |
| Dermal: | No information available | rabbit | LD ₅₀ | - | >3.500mg/kg (ethylene glycol) |

| | | | | | |
|---------------|-----------------------------|----------------------|--------------|----------|---|
| Trade name: | OG-6 REAGENT, PAP 2A | | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: | 2 |

| | | | | | |
|-------------|--------------------------|-----|------------------|---------------|-----------------------|
| Inhalation: | No information available | rat | LC ₅₀ | 4 h (ethanol) | 20.000 mg/l (ethanol) |
|-------------|--------------------------|-----|------------------|---------------|-----------------------|

Specific target organ toxicity - single exposure (STOT-SE):

| | Specific effects | Target organ | Note |
|-------------|--------------------------|--------------------------|------|
| Oral: | No information available | No information available | - |
| Dermal: | No information available | No information available | - |
| Inhalation: | No information available | No information available | - |

Aspiration hazard: No information available

Irritation and corrosion

| | Exposure time | Species | Evaluation | Method | Note |
|-------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|------|
| Skin corrosion/irritation | No information available | No information available | No information available | No information available | - |
| Serious eye damage/irritation | No information available | No information available | No information available | No information available | - |

Sensitization

| | |
|----------------------------|--------------------------|
| Skin sensitization: | No information available |
| Respiratory sensitization: | No information available |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|----------------------|--|
| Oral exposure: | Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation. |
| Dermal exposure: | Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin. |
| Inhalation exposure: | Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea. |
| Eye exposure: | Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation. |

Repeated dose toxicity (subacute, subchronic, chronic)

| | Dose | Exposure time | Species | Method | Evaluation | Note |
|--|------|---------------|---------|--------|------------|------|
|--|------|---------------|---------|--------|------------|------|

| | | | | | |
|---------------|-----------------------------|----------------------|--------------|----------|---|
| Trade name: | OG-6 REAGENT, PAP 2A | | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: | 2 |

| | | | | | | |
|-----------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| 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 | - |
| 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)

| | | | | | |
|---------------|-----------------------------|----------------------|--------------|----------|---|
| Trade name: | OG-6 REAGENT, PAP 2A | | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: | 2 |

| | |
|--|--------------------------|
| Carcinogenicity: | No information available |
| Mutagenicity <i>in-vitro</i> : | No information available |
| Genotoxicity: | No information available |
| Mutagenicity <i>in-vivo</i> : | No information available |
| Germ cell mutagenicity : | No information available |
| Reproductive toxicity: | No information available |
| | |
| Summary of evaluation of the CMR properties; : | No information available |
| | |
| 11.2. Practical experiences: | |
| Classification observations: | No information available |
| Other observations: | No information available |
| | |
| 11.3. General notes: | |
| - | |

| SECTION 12. Ecological information | | | | | | |
|---|------------------|---------------|--------------------------|--------------------------|-------------------------------------|------|
| 12.1. Toxicity | | | | | | |
| Acute (short-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
| Fish | LC ₅₀ | 96 hours | Fish | No information available | 72.860 mg/l (ethylene glycol) | - |
| Crustacea: | EC ₅₀ | 48 hours | water flea | No information available | >100 mg/l (ethylene glycol) | - |
| Algae/aquatic plants: | IC ₅₀ | 72 hours | algae | No information available | 6.500-13.000 mg/l (ethylene glycol) | - |
| Other organisms | - | - | - | - | - | - |
| Chronic (long-term) toxicity | Doza | Exposure time | Species | Method | Evaluation | Note |
| Fish | LC ₅₀ | 96 hours | No information available | No information available | No information available | - |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | - |

| | | | | | |
|---------------|-----------------------------|----------------------|--------------|----------|---|
| Trade name: | OG-6 REAGENT, PAP 2A | | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: | 2 |

| | | | | | | |
|----------------------|------------------|----------|--------------------------|--------------------------|--------------------------|---|
| Algae/aquatic plants | IC ₅₀ | 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 |
|---------------|-------------|--------|------------|------|
| - | - | - | - | - |

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log K_{ow})

| Value | Concentration | pH | °C | Method | Evaluation | Note |
|-------|---------------|----|----|--------|------------|------|
| - | - | - | - | - | - | - |

Bioconcentration Factor (BCF)

| Value | Species | Method | Evaluation | Note |
|--------------------------|--------------------------|--------------------------|--------------------------|------|
| No information available | No information available | No information available | No information available | - |

Chronic ecotoxicity

| | | | | | |
|---------------|-----------------------------|----------------------|--------------|----------|---|
| Trade name: | OG-6 REAGENT, PAP 2A | | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: | 2 |

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

12.6. Other adverse effects

No information available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
| Trade name: | OG-6 REAGENT, PAP 2A | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: 2 |

| | |
|---------|--|
| | 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 Low: Packaging that contains residual hazardous substances or is contaminated with hazardous substances |
| 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. |
| 13.1.6. | Relevant Community provisions: Disposal must be made according to official regulations. |

SECTION 14. Transport information

| | |
|---|--------------------------|
| Transporting/shipment by road (ADR) | |
| UN number | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |
| Transporting/shipment by rail (RID) | |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |
| Transporting/shipment by inland waterways (ADN) | |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
| Trade name: | OG-6 REAGENT, PAP 2A | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: 2 |

| | |
|-------------------------------|--------------------------|
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |

Transporting/shipment by sea (IMDG)

| | |
|--|--------------------------|
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |
| Transport in bulk according to Annex II of MARPOL73/78 and the IBC code: | - |

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

| | |
|-------------------------------|--------------------------|
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |

| | |
|----------------------|---|
| Further information: | - |
|----------------------|---|

SECTION 15. Regulatory information

| | | |
|-------|--|---|
| 15.1. | Safety, health and environmental regulations/legislation specific for the substance or mixture | |
| | EU regulations | |
| | Authorisation and/or restrictions on use | |
| | Authorisations: | - |
| | Restrictions: | - |

| | | | | |
|---------------|-----------------------------|----------------------|--------------|------------|
| Trade name: | OG-6 REAGENT, PAP 2A | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: 2 |

| | |
|--|---|
| Other EU regulations: | <p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</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> |
| 15.2. | Chemical safety assessment |
| | None |

| SECTION 16. Other information | | | | | | | | | | | | | | | | |
|--------------------------------------|--|--|--------------------------|------------------------------------|---|------|---|--|------|------------------|--|------|---------------------------|--|---------|--|
| 16.1. | Indication of changes: - | | | | | | | | | | | | | | | |
| 16.2. | <table border="0"> <tr> <td>Abbreviations and acronyms:</td> <td>PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td></td> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td></td> <td>LD50</td> <td>Lethal dose, 50%</td> </tr> <tr> <td></td> <td>LC50</td> <td>Lethal concentration, 50%</td> </tr> <tr> <td></td> <td>STOT-SE</td> <td>Specific target organ toxicity – single exposure</td> </tr> </table> | Abbreviations and acronyms: | PBT | Stable, bioaccumulative and toxic | | vPvB | Strongly stable and strongly bioaccumulative. | | LD50 | Lethal dose, 50% | | LC50 | Lethal concentration, 50% | | STOT-SE | Specific target organ toxicity – single exposure |
| Abbreviations and acronyms: | PBT | Stable, bioaccumulative and toxic | | | | | | | | | | | | | | |
| | vPvB | Strongly stable and strongly bioaccumulative. | | | | | | | | | | | | | | |
| | LD50 | Lethal dose, 50% | | | | | | | | | | | | | | |
| | LC50 | Lethal concentration, 50% | | | | | | | | | | | | | | |
| | STOT-SE | Specific target organ toxicity – single exposure | | | | | | | | | | | | | | |
| 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) | | | | | | | | | | | | | | | |
| | <table border="0"> <tr> <td>Classification</td> <td>Classification procedure</td> </tr> <tr> <td>-</td> <td>-</td> </tr> </table> | Classification | Classification procedure | - | - | | | | | | | | | | | |
| Classification | Classification procedure | | | | | | | | | | | | | | | |
| - | - | | | | | | | | | | | | | | | |
| 16.5. | Relevant H statements (number and full text) | | | | | | | | | | | | | | | |
| | <table border="0"> <tr> <td>H:</td> <td>H225</td> <td>Highly flammable liquid and vapor.</td> </tr> <tr> <td></td> <td>H302</td> <td>Harmful if swallowed.</td> </tr> </table> | H: | H225 | Highly flammable liquid and vapor. | | H302 | Harmful if swallowed. | | | | | | | | | |
| H: | H225 | Highly flammable liquid and vapor. | | | | | | | | | | | | | | |
| | H302 | Harmful if swallowed. | | | | | | | | | | | | | | |

| | | | | | |
|---------------|-----------------------------|----------------------|--------------|----------|---|
| Trade name: | OG-6 REAGENT, PAP 2A | | | | |
| Product code: | OG6-OT-X** | Date of compilation: | 05 June 2019 | Version: | 2 |

| | | |
|-------|----------------------|---|
| 16.6. | Training advice: | - |
| 16.7. | Further information: | <p>** "X" in the product code marks different volumes (different packaging 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> |

ANNEX: Exposure scenario resulting to Chemical safety assessment


-

| | | | | |
|---------------|------------------------------|----------------------|--------------|------------|
| Trade name: | EA 50 REAGENT, PAP 3B | | | |
| Product code: | EA50-OT-X** | Date of compilation: | 05 June 2019 | Version: 2 |

| SECTION 1: Identification of the substance/mixture and of the company/undertaking | | |
|--|---|--|
| 1.1. | Product identifier | |
| | Trade name: | EA 50 REAGENT, PAP 3B |
| | Chemical name: | - |
| | Catalogue number: | EA50-OT-X** |
| 1.2. | Relevant identified uses of the substance or mixture and uses advised against | |
| | Uses: | Cytoplasmic staining reagent acc. to Papanicolaou. |
| | 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 |
| | Telefax: | +385 1 2404039 |
| | E-mail of competent person: | msds@biognost.hr |
| | National contact: | - |
| 1.4. | Emergency telephone numbers | |
| | 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 statement*: |
| | Flam. Liq. 2 | H225 |
| 2.1.2. | Additional information | |
| | - | |
| *For full text of Hazard- and EU Hazard-statements: see Section 16. | | |
| 2.2. | Label elements | |
| | Product identification: | EA 50 REAGENT, PAP 3B |
| | Identification number: | - |
| | Authorisation number: | - |

| | | | | |
|---------------|------------------------------|----------------------|--------------|------------|
| Trade name: | EA 50 REAGENT, PAP 3B | | | |
| Product code: | EA50-OT-X** | Date of compilation: | 05 June 2019 | Version: 2 |

| | |
|---------------------------------------|---|
| Hazard pictograms: |  |
| | GHS02 |
| Signal word: | Danger |
| Warning statement: | H225 Highly flammable liquid and vapor. |
| Precautionary statement: | P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. |
| Supplemental hazard information (EU): | - |
| 2.3. Other hazards | |
| - | |

| SECTION 3. Composition/information on ingredients | | | | |
|--|-----------------------|-----------------------------|---------------------|--|
| CAS/EC/ Index number | REACH Registration No | Weight % content (or range) | Identification name | Classification according to Regulation (EC) No 1272/2008 (CLP) |
| 64-17-5/ 200-578-6/ 603-002-00-5 | - | ≥ 60 | ethanol | Flam. Liq. 2; H225 |
| 107-21-1/ 203-473-3/ 603-027-00-1 | - | < 20 | ethylene glycol | Acute Tox. 4; H302 |

| SECTION 4. First aid measures | |
|--------------------------------------|---|
| 4.1. | Description of first aid measures |
| General notes: | If the suggested first aid measures do not prove sufficient, seek medical attention. |
| Following inhalation: | Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen. |
| Following skin contact: | Remove all contaminated clothes/footwear. Thoroughly wash with water for at least 15 minutes. |
| Following eye contact: | Rinse the eyes using mild jet of clean water for at least 20 minutes with the eyelids held wide open. |

| | | | | |
|---------------|------------------------------|----------------------|--------------|------------|
| Trade name: | EA 50 REAGENT, PAP 3B | | | |
| Product code: | EA50-OT-X** | Date of compilation: | 05 June 2019 | Version: 2 |

| | | |
|-------------|---|--|
| | Following swallowing: | Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital. |
| | Self-protection of the first aider | - |
| 4.2. | Most important symptoms and effects, both acute and delayed | |
| | Following inhalation: | Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea. |
| | Following skin contact: | Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking. |
| | Following eye contact: | Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain. |
| | Following swallowing: | Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting. |
| 4.3. | Indication of any immediate medical attention and special treatment needed | |
| | No information available | |

| | | |
|---|--|---|
| SECTION 5. Firefighting measures | | |
| 5.1. | Extinguishing media | |
| | Suitable extinguishing media: | Small fire - water spray, dry powder, alcohol-resistant foam, CO2 Large fire - water spray or alcohol-resistant foam |
| | Unsuitable extinguishing media: | Water with full jet |
| 5.2. | Special hazards arising from the substance or mixture | |
| | Hazardous byproducts of fire: | Incomplete combustion of the product. |
| 5.3. | Advice for firefighters | |
| | Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing). | |
| 5.4. | Additional information | |
| | Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media. | |

| | | |
|---|--|--|
| SECTION 6. Accidental release measures | | |
| 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). |

| | | | | |
|---------------|------------------------------|----------------------|--------------|------------|
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| | | |
|--------|---|--|
| | Accident prevention methods: | Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources. |
| | Emergency procedures: | Mark the area using proper signs. |
| 6.1.2. | For emergency responders: | |
| | Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing). | |
| 6.2. | Environmental precautions: | |
| | Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater. | |
| 6.3. | Methods and materials for containment and cleaning up | |
| 6.3.1. | Bundling, covering of drains; capping procedures: | Sand protective barrier or barriers made of similar materials |
| 6.3.2. | Cleaning up: | Sawdust, sand, mineral adsorbents |
| 6.3.3. | Other information: | Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112). Do not use incompatible materials (see Section 10). |
| 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. | |

| | | |
|--|--|---|
| SECTION 7. Handling and storage | | |
| 7.1. | Precautions for safe handling | |
| 7.1.1. | Protection measures | |
| | Measures to prevent fire: | Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. 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: | Protect against electrostatic charges. |
| 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 at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight. |

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| | | |
|---|--|--|
| 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 10). | |
| 7.3. Specific end use(s) | | |
| 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 ³ | |
| Ethanol | 64-17-5 | 1000/- | 1900/- | No information available |
| Ethylene glycol | 107-21-1 | 20/40 | 52/104 | No information available |

| | |
|------------|---|
| Substance: | - |
| EC No: | - |
| CAS No: | - |

DNEL

Industrial

| Route of exposure: | Acute effect local | Acute effect systemic | Chronic effect local | Chronic effect systemic |
|--------------------|--------------------|-----------------------|-----------------------------|--|
| Oral | - | - | - | - |
| Inhalation | - | - | 35 mg/ kg (ethylene glycol) | 950 mg/m ³ (ethanol) |
| Dermal | - | - | - | 343 mg/kg (ethanol) 106 mg/kg (ethylene glycol) |

| | |
|--|---|
| Critical physical parameters: solubility, flammability, corrosivity: | - |
|--|---|

Consumer

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

| | | | | |
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| | | | | |
|------------|---|---|------------------------------|---|
| Inhalation | - | - | 7 mg/kg (ethylene glycol) | 950 mg/m ³ (ethanol) |
| Dermal | - | - | - | 343 mg/kg (ethanol) 53 mg/kg (ethylene glycol) |

| PNEC | |
|------------------------------------|--|
| Environmental protection target | PNEC |
| Fresh water | 0.96 mg/l (ethanol) 10 mg/l (ethylene glycol) |
| Freshwater sediments | 3.6 mg/kg (ethanol) 37 mg/kg (ethylene glycol) |
| Marine water | 0.79 mg/l (ethanol) 1 mg/kg (ethylene glycol) |
| Marine sediments | 3.7 mg/kg (ethylene glycol) |
| Food chain | no information available |
| Microorganisms in sewage treatment | no information available |
| Soil (agricultural) | 0.63 mg/kg (ethanol) 1.53 mg/kg (ethylene glycol) |
| Air | no information available |

| | |
|--|--|
| 8.2. Exposure controls | |
| 8.2.1. Appropriate engineering controls | |
| Substance/mixture related measures to prevent exposure during identified uses: | Do not eat, drink or smoke in the workspace. Use personal protective equipment. |
| 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: | See Section 7.2 |
| 8.2.2. Personal protection equipment | |
| 8.2.2.1. Eye and face protection: | Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air. |
| 8.2.2.2. Skin protection | |

| | | | | |
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| | | |
|----------|---|---|
| | Hand protection: | Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min |
| | Other skin protection: | During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material. |
| 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 | | | |
|--|---|--------------------------|--------------------------|
| 9.1. Information on basic physical and chemical properties | | | |
| | | Value | Method |
| | Physical state: | liquid | no information available |
| | Colour: | violet green | no information available |
| | Odour: | ethanol like | no information available |
| | Odour threshold; | no information available | no information available |
| | pH: | 5.2-5.8 | no information available |
| | Melting point / freezing point; | no information available | no information available |
| | Initial boiling point and boiling range: | no information available | no information available |
| | Flash point: | 21°C | no information available |
| | Evaporation rate: | no information available | no information available |
| | Flammability (solid, gas): | no information available | no information available |
| | Upper/lower flammability or explosive limits: | no information available | no information available |
| | Vapour pressure: | no information available | no information available |

| | | | | | |
|---------------|------------------------------|----------------------|--------------|----------|---|
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| | | |
|---|--------------------------|--------------------------|
| Vapour density: | no information available | no information available |
| Relative density | no information available | no information available |
| Bulk density: | No information available | no information available |
| Solubility(ies): | no information available | no information available |
| Partition coefficient: n-octanol/water (log Kow): | no information available | no information available |
| Auto-ignition temperature: | no information available | no information available |
| Decomposition temperature: | no information available | no information available |
| Viscosity: | no information available | no information available |
| Explosive properties: | no information available | no information available |
| Oxidising properties: | no information available | no information available |
| 9.2. | Other information | |
| | - | |

| SECTION 10.: Stability and reactivity | | |
|--|-------------------------------------|---|
| 10.1. | Reactivity: | The product is stable under normal working and storage conditions. |
| 10.2. | Chemical stability: | The product is chemically stable under standard ambient conditions of storing and using. |
| 10.3. | Possibility of hazardous reactions: | Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances. |
| 10.4. | Conditions to avoid: | Avoid heat, sparks, open flames and other ignition sources. |
| 10.5. | Incompatible materials: | Oxidants, acids, alkali metals. |
| 10.6. | Hazardous decomposition products: | Non-degradable if used in the described manner. |

| SECTION 11. Toxicological information | | | | | |
|--|--------------------------|---------|---|------------------|--|
| 11.1. Information on toxicological effects | | | | | |
| Acute toxicity: | | | | | |
| Route of exposure: | Method | Species | Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture} | Exposure time | Results |
| Oral: | No information available | rat | LD ₅₀ | - | 7.060 mg/kg (ethanol) 7.712 mg/kg (ethylene glycol) |
| Dermal: | No information available | rabbit | LD ₅₀ | - | >3.500mg/kg (ethylene glycol) |
| Inhalation: | No information available | rat | LC ₅₀ | 4 h (ethanol) | 20.000 mg/l (ethanol) |

| | | | | | |
|---------------|------------------------------|----------------------|--------------|----------|---|
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| | | | | | | |
|--|--|--------------------------|--------------------------|--------------------------|------------|------|
| Specific target organ toxicity - single exposure (STOT-SE): | | | | | | |
| | Specific effects | | Target organ | | Note | |
| Oral: | No information available | | No information available | | - | |
| Dermal: | No information available | | No information available | | - | |
| Inhalation: | No information available | | No information available | | - | |
| Aspiration hazard: | | | | | | |
| | | | No information available | | | |
| Irritation and corrosion | | | | | | |
| | Exposure time | Species | Evaluation | Method | Note | |
| Skin corrosion/irritation | No information available | No information available | No information available | No information available | - | |
| Serious eye damage/irritation | No information available | No information available | No information available | No information available | - | |
| Sensitization | | | | | | |
| Skin sensitization: | No information available | | | | | |
| Respiratory sensitization: | No information available | | | | | |
| Symptoms related to the physical, chemical and toxicological characteristics | | | | | | |
| Oral exposure: | Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation. | | | | | |
| Dermal exposure: | Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin. | | | | | |
| Inhalation exposure: | Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea. | | | | | |
| Eye exposure: | Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation. | | | | | |
| Repeated dose toxicity (subacute, subchronic, chronic) | | | | | | |
| | Dose | Exposure time | Species | Method | Evaluation | Note |

| | | | | | |
|---------------|------------------------------|----------------------|--------------|----------|---|
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| | | | | | | |
|-----------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| 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 | - |
| 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)

| | | | | | |
|---------------|------------------------------|----------------------|--------------|----------|---|
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| | |
|--|--------------------------|
| Carcinogenicity: | No information available |
| Mutagenicity <i>in-vitro</i> : | No information available |
| Genotoxicity: | No information available |
| Mutagenicity <i>in-vivo</i> : | No information available |
| Germ cell mutagenicity : | No information available |
| Reproductive toxicity: | No information available |
| | |
| Summary of evaluation of the CMR properties; : | No information available |
| | |
| 11.2. Practical experiences: | |
| Classification observations: | No information available |
| Other observations: | No information available |
| | |
| 11.3. General notes: | |
| - | |

| SECTION 12. Ecological information | | | | | | |
|---|------------------|---------------|--------------------------|--------------------------|-------------------------------------|------|
| 12.1. Toxicity | | | | | | |
| Acute (short-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
| Fish | LC ₅₀ | 96 hours | Fish | No information available | 72.860 mg/l (ethylene glycol) | - |
| Crustacea: | EC ₅₀ | 48 hours | water flea | No information available | >100 mg/l (ethylene glycol) | - |
| Algae/aquatic plants: | IC ₅₀ | 72 hours | algae | No information available | 6.500-13.000 mg/l (ethylene glycol) | - |
| Other organisms | - | - | - | - | - | - |
| Chronic (long-term) toxicity | Doza | Exposure time | Species | Method | Evaluation | Note |
| Fish | LC ₅₀ | 96 hours | No information available | No information available | No information available | - |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | - |

| | | | | | |
|---------------|------------------------------|----------------------|--------------|----------|---|
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| | | | | | | |
|----------------------|------------------|----------|--------------------------|--------------------------|--------------------------|---|
| Algae/aquatic plants | IC ₅₀ | 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 |
|---------------|-------------|--------|------------|------|
| - | - | - | - | - |

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

| Value | Concentration | pH | °C | Method | Evaluation | Note |
|-------|---------------|----|----|--------|------------|------|
| - | - | - | - | - | - | - |

Bioconcentration Factor (BCF)

| Value | Species | Method | Evaluation | Note |
|--------------------------|--------------------------|--------------------------|--------------------------|------|
| No information available | No information available | No information available | No information available | - |

Chronic ecotoxicity

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

12.6. Other adverse effects

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

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

| | | | | |
|---------------|------------------------------|----------------------|--------------|------------|
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| | |
|---------|--|
| | 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 Low: Packaging that contains residual hazardous substances or is contaminated with hazardous substances |
| 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. |
| 13.1.6. | Relevant Community provisions: Disposal must be made according to official regulations. |

SECTION 14. Transport information

| | |
|---|--------------------------|
| Transporting/shipment by road (ADR) | |
| UN number | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |
| Transporting/shipment by rail (RID) | |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |
| Transporting/shipment by inland waterways (ADN) | |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |

| | | | | |
|---------------|------------------------------|----------------------|--------------|------------|
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| | |
|-------------------------------|--------------------------|
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |

Transporting/shipment by sea (IMDG)

| | |
|--|--------------------------|
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |
| Transport in bulk according to Annex II of MARPOL73/78 and the IBC code: | - |

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

| | |
|-------------------------------|--------------------------|
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmental hazards: | No information available |
| Special precautions for user: | - |

| | |
|----------------------|---|
| Further information: | - |
|----------------------|---|

SECTION 15. Regulatory information

| | | |
|-------|--|---|
| 15.1. | Safety, health and environmental regulations/legislation specific for the substance or mixture | |
| | EU regulations | |
| | Authorisation and/or restrictions on use | |
| | Authorisations: | - |
| | Restrictions: | - |

| | | | | |
|---------------|------------------------------|----------------------|--------------|------------|
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| | |
|--|---|
| Other EU regulations: | <p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</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> |
| 15.2. Chemical safety assessment | |
| | None |

| SECTION 16. Other information | | | | | | | | | | | |
|---|---|------|------------------------------------|------|---|------|------------------|------|---------------------------|---------|--|
| 16.1. Indication of changes: | - | | | | | | | | | | |
| 16.2. Abbreviations and acronyms: | <table border="0"> <tr> <td>PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td>LD50</td> <td>Lethal dose, 50%</td> </tr> <tr> <td>LC50</td> <td>Lethal concentration, 50%</td> </tr> <tr> <td>STOT-SE</td> <td>Specific target organ toxicity – single exposure</td> </tr> </table> | PBT | Stable, bioaccumulative and toxic | vPvB | Strongly stable and strongly bioaccumulative. | LD50 | Lethal dose, 50% | LC50 | Lethal concentration, 50% | STOT-SE | Specific target organ toxicity – single exposure |
| PBT | Stable, bioaccumulative and toxic | | | | | | | | | | |
| vPvB | Strongly stable and strongly bioaccumulative. | | | | | | | | | | |
| LD50 | Lethal dose, 50% | | | | | | | | | | |
| LC50 | Lethal concentration, 50% | | | | | | | | | | |
| STOT-SE | Specific target organ toxicity – single exposure | | | | | | | | | | |
| 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: | <table border="0"> <tr> <td>H225</td> <td>Highly flammable liquid and vapor.</td> </tr> <tr> <td>H302</td> <td>Harmful if swallowed.</td> </tr> </table> | H225 | Highly flammable liquid and vapor. | H302 | Harmful if swallowed. | | | | | | |
| H225 | Highly flammable liquid and vapor. | | | | | | | | | | |
| H302 | Harmful if swallowed. | | | | | | | | | | |

| | | | | | |
|---------------|------------------------------|----------------------|--------------|----------|---|
| Trade name: | EA 50 REAGENT, PAP 3B | | | | |
| Product code: | EA50-OT-X** | Date of compilation: | 05 June 2019 | Version: | 2 |

| | | |
|-------|----------------------|---|
| 16.6. | Training advice: | - |
| 16.7. | Further information: | <p>** "X" in the product code marks different volumes (different packaging 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> |

ANNEX: Exposure scenario resulting to Chemical safety assessment


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| | | | | | |
|---------------|---------------------|----------------|-------------|----------|--|
| Trading name: | HISTANOL 100 | | | | |
| Product code: | H100-X** | Revision date: | 13 May 2019 | Version: | |

| SECTION 1: Identification of the substance/mixture and of the company/undertaking | |
|--|---|
| 1.1 | Product identifier |
| | Trading name: HISTANOL 100 |
| | Chemical name: Ethyl alcohol |
| | Catalogue number: H100-X** |
| 1.2 | Relevant identified uses of the substance or mixture and uses advised against |
| | Uses: For use in histocytology and cytology sample processing. |
| | 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 |
| | Telefax.: +385 1 2404039 |
| | e-mail of competent person: msds@biognost.hr |
| | 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: Flam. Liq. 2 | Hazard statements*: H225 |
| 2.1.2. | Additional information | |
| | - | |
| *For full text of Hazard- and EU Hazard-statements: see SECTION 16 | | |
| 2.2 | Label elements | |
| | Product identification: HISTANOL 100 | |
| | Identification number: - | |
| | Authorization number: - | |

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| | |
|---------------------------------------|---|
| Hazard pictograms: |  |
| | GHS02 |
| Signal word: | Danger |
| Hazard statements: | H225 Highly flammable liquid and vapor. |
| Precautionary statements: | P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. |
| Supplemental hazard information (EU): | - |
| 2.3 Other hazards | |
| - | |

SECTION 3. Composition/information on ingredients

| CAS/EC/ Index number | REACH Registration No | Weight % content (or range) | Identification name | Classification according to Regulation (EC) No 1272/2008 (CLP) |
|--|-----------------------|-----------------------------|---------------------|--|
| 64-17-5/ 200-578-6/ 603-002-00-5 | 01-2119457610-43-xxxx | ≤ 100% | ethanol | Flam. Liq. 2; H225 |

SECTION 4. First aid measures

| | |
|--|---|
| 4.1 Description of first aid measures | |
| General notes: | If the suggested first aid measures do not prove sufficient, seek medical attention. |
| Following inhalation: | Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen. |
| Following skin contact: | Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain. |
| Following eye contact: | Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist. |

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| | Following ingestion: | Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital. |
| | Self-protection of the first aider: | - |
| 4.2 | Most important symptoms and effects, both acute and delayed | |
| | Following inhalation: | Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea. |
| | Following skin contact: | Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking. |
| | Following eye contact: | Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain. |
| | Following ingestion: | Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting. |
| 4.3 | Indication of any immediate medical attention and special treatment needed | |
| | - | |

| | | |
|---|---|---|
| SECTION 5. Firefighting measures | | |
| 5.1 | Extinguishing media | |
| | Suitable extinguishing media: | Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam |
| | Unsuitable extinguishing media: | Water with full jet |
| 5.2 | Special hazards arising from the substance or mixture | |
| | Hazardous combustion products: | Formation of toxic gases is possible during heating or in case of fire. |
| 5.3 | Advice for firefighters | |
| | Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. | |
| 5.4 | Additional information | |
| | Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media. | |

| | | |
|---|--|---|
| SECTION 6. Accidental release measures | | |
| 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. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources. |

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| | Emergency procedures: | Mark the area using proper signs. |
| 6.1.2. | For emergency responders: | |
| | Use protective equipment; in case of inadequate ventilation use adequate airways 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 protective barrier or barriers made of similar materials. |
| 6.3.2. | Cleaning up: | Where possible, the substance can be absorbed by using absorbing material. 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: | Secure proper ventilation. Do not use incompatible materials (see Section 10). |
| 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. | |

| SECTION 7. Handling and storage | | |
|--|--|---|
| 7.1 | Precautions for safe handling | |
| 7.1.1. | Protection measures | |
| | Measures to prevent fire: | Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. 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: | Protect against electrostatic charges. |
| 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 at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight. |

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|---|--|
| 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 10). |
| 7.3 Specific end use(s) | |
| 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 ³ | |
| Ethanol | 64-17-5 | 1000/- | 1900/- | - |
| 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 | - | - | - | 950 mg/m ³ (ethanol) |
| Dermal | - | - | - | 343 mg/kg (ethanol) |
| Critical physical parameters: solubility, flammability, corrosivity: - | | | | |
| Consumer | | | | |
| Route of exposure: | Acute effect local | Acute effect systemic | Chronic effect local | Chronic effect systemic |
| Oral | - | - | - | - |
| Inhalation | - | - | - | 114 mg/m ³ (ethanol) |
| Dermal | - | - | - | 206 mg/kg (ethanol) |
| PNEC | | | | |

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| Environmental protection target | PNEC |
|------------------------------------|--------------------------|
| Fresh water | 0.96 mg/l (ethanol) |
| Freshwater sediments | 3.6 mg/kg (ethanol) |
| Marine water | 0.79 mg/l (ethanol) |
| Marine sediments | no information available |
| Food chain | no information available |
| Microorganisms in sewage treatment | no information available |
| Soil (agricultural) | 0.63 mg/kg (ethanol) |
| 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: | In accordance with Section 7. |
| | 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. Secure stations for rinsing eyes and showering. |
| 8.2.2. | Personal protection equipment | |
| 8.2.2.1. | Eye and face protection: | Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air. |
| 8.2.2.2. | Skin protection | |
| | Hand protection: | The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min |
| | Other skin protection: | During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material. |

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| 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

| | | | |
|-----|---|-------------------------------------|--------------------------|
| 9.1 | Information on basic physical and chemical properties | | |
| | | Value | Method |
| | Physical state: | liquid | No information available |
| | Colour: | colourless | No information available |
| | Odour: | alcohol like | No information available |
| | Odor threshold: | No information available | No information available |
| | pH: | No information available | No information available |
| | Melting point / freezing point: | -114.5°C | No information available |
| | Initial boiling point and boiling range: | 78 °C | No information available |
| | Flash point: | 13 °C | No information available |
| | Evaporation rate: | No information available | No information available |
| | Flammability (solid, gas): | No information available | No information available |
| | Upper/lower flammability or explosive limits: | lower: 3.5 Vol % upper: 15 Vol % | No information available |
| | Vapour pressure: | 59 hPa | No information available |
| | Vapour density: | No information available | No information available |
| | Relative density: | 0.711 – 0.87778 (20°C) | No information available |
| | Bulk density: | No information available | No information available |
| | Solubility(ies): | 1 g/l (20°C) | No information available |
| | Partition coefficient: n-octanol/water (log Kow): | No information available | No information available |
| | Auto-ignition temperature: | Product is not selfigniting | No information available |

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| | | |
|----------------------------|---|--------------------------|
| Decomposition temperature: | No information available | No information available |
| Viscosity: | 1.2 mPas (dynamic at 20°C) | No information available |
| Explosive properties: | Product is not explosive. However, formation of explosive air/vapour mixtures are possible. | No information available |
| Oxidising properties: | No information available | No information available |
| 9.2 | Other information | |
| | Ignition temperature: 425 °C | |

| 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 (room temperature). |
| 10.3 | Possibility of hazardous reactions: | No dangerous reactions known. |
| 10.4 | Conditions to avoid: | Avoid heat, sparks, open flames and other ignition sources. |
| 10.5 | Incompatible materials: | No further relevant information available. |
| 10.6 | Hazardous decomposition products: | No dangerous decomposition products known. |

| SECTION 11. Toxicological information | | | | | |
|---|--------------------------|---------------|---|---------------|-------------|
| 11.1 Information on toxicological effects | | | | | |
| Acute toxicity: | | | | | |
| Route of exposure: | Method | Species | Dose LD ₅₀ /LC ₅₀ or ATE _{mix} | Exposure time | Results |
| Oral: | - | rat (ethanol) | LD ₅₀ | - | 7.060 mg/kg |
| Dermal: | - | - | - | - | - |
| Inhalation: | - | rat (ethanol) | LC ₅₀ | 4 h | 20.000 mg/l |
| Specific target organ toxicity – single exposure (STOT SE): | | | | | |
| | Specific effects | | Target organ | | Note |
| Oral: | No information available | | No information available | | - |
| Dermal: | No information available | | No information available | | - |
| Inhalation: | No information available | | No information available | | - |
| Aspiration hazard: | | | | | |
| | | | No information available. | | |
| Irritation and corrosion | | | | | |

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| | Exposure time | Species | Evaluation | Method | Note |
|-------------------------------|---------------|---------|------------|--------|------|
| Skin corrosion/irritation: | - | - | - | - | - |
| Serious eye damage/irritation | - | - | - | - | - |

Sensitization

| | |
|----------------------------|---------------------------|
| Skin sensitization: | No information available. |
| Respiratory sensitization: | No information available. |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|----------------------|---------------------------|
| Oral exposure: | No information available. |
| Dermal exposure: | No information available. |
| Inhalation exposure: | No information available. |
| Eye exposure: | No information available. |

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 | - |

| | | | | | | |
|---------------|---------------------|----------------|-------------|----------|--|--|
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| | | | | | | |
|--------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| 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 | - |

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|---|--|--|--|--|--|--|
| 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 | - |
| 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 | - |

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|--|--|--|--|--|--|--|
| CMR effects (carcinogenicity; mutagenicity; reproductive toxicity) | | | | | | |
|--|--|--|--|--|--|--|

| | | | | | | |
|--------------------------------|---|--|--|--|--|--|
| Carcinogenicity: | Based on available data, the classification criteria are not met. | | | | | |
| Mutagenicity <i>in vitro</i> : | Based on available data, the classification criteria are not met. | | | | | |
| Genotoxicity: | Based on available data, the classification criteria are not met. | | | | | |
| Mutagenicity <i>in vivo</i> : | Based on available data, the classification criteria are not met. | | | | | |
| Germ cell mutagenicity: | Based on available data, the classification criteria are not met. | | | | | |
| Reproductive toxicity: | Based on available data, the classification criteria are not met. | | | | | |

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| Summary of evaluation of the CMR properties: | Based on available data, the classification criteria are not met. | | | | | |
|--|---|--|--|--|--|--|

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|-------------|-------------------------------|--|--|--|--|--|
| 11.2 | Practical experiences: | | | | | |
|-------------|-------------------------------|--|--|--|--|--|

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|------------------------------|--------------------------|--|--|--|--|--|
| Classification observations: | No information available | | | | | |
|------------------------------|--------------------------|--|--|--|--|--|

| | | | | | | |
|---------------------|--------------------------|--|--|--|--|--|
| Other observations: | No information available | | | | | |
|---------------------|--------------------------|--|--|--|--|--|

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| 11.3 | General notes: | | | | | |
|-------------|-----------------------|--|--|--|--|--|

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| - | | | | | | |
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| SECTION 12. Ecological information | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|------|
| 12.1 Toxicity | | | | | | |
| Acute (short-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
| Fish | LC ₅₀ | 96 hours | No information available | No information available | No information available | - |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | - |
| Algae/aquatic plants | IC ₅₀ | 4 days | No information available | No information available | No information available | - |
| Other organisms | - | - | - | - | - | - |
| Chronic (long-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
| Fish | LC ₅₀ | 96 hours | No information available | No information available | No information available | - |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | - |
| Algae/aquatic plants | IC ₅₀ | 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 | | |

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|---------------|---------------------|----------------|-------------|----------|
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|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 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 |
| - | - | - | - | - | - | - |
| | | | | | | |

Bioconcentration factor (BCF)

| Value | Species | Method | Evaluation | Note |
|--------------------------|--------------------------|--------------------------|--------------------------|------|
| 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 ₅₀ | No information available | No information available | No information available | No information available | - |
| Chronic toxicity on crustacea (<i>Daphnia</i>) | EC ₅₀ | 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 | - | | |

| | | | | | |
|---------------|---------------------|----------------|-------------|----------|--|
| Trading name: | HISTANOL 100 | | | | |
| Product code: | H100-X** | Revision date: | 13 May 2019 | Version: | |

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

| | |
|-------------|---|
| 12.5 | Results of PBT and vPvB assessment |
| | Not applicable. |

| | |
|-------------|--|
| 12.6 | Other adverse effects |
| | No further relevant information available. |

SECTION 13. Disposal considerations

| | |
|-------------|--------------------------------|
| 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: |
| | Packaging that contains residual hazardous substances or is contaminated with hazardous substances |

| | |
|----------------|--|
| 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. |

| | | | | |
|---------------|---------------------|----------------|-------------|----------|
| Trading name: | HISTANOL 100 | | | |
| Product code: | H100-X** | Revision date: | 13 May 2019 | Version: |

| | |
|---------|--|
| 13.1.6. | Relevant Community provisions: |
| | Disposal must be made according to official regulations. |

SECTION 14 TRANSPORT INFORMATION

| | |
|---|---|
| | Transporting/shipment by road (ADR) |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| | Transporting/shipment by rail (RID) |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| | Inland waterway transport (ADN) |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| | Transporting/shipment by sea (IMDG) |
| UN number: | 1170 |
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code: | - |
| | Transporting/shipment by air (ICAO-TI/IATA-DGR) |
| UN number: | 1170 |

| | | | | |
|---------------|---------------------|----------------|-------------|----------|
| Trading name: | HISTANOL 100 | | | |
| Product code: | H100-X** | Revision date: | 13 May 2019 | Version: |

| | |
|-------------------------------|------------------|
| UN proper shipping name: | Ethanol solution |
| Transport hazard class(es): | 3 |
| Packing group: | II |
| Environmentally hazardous: | - |
| Special precautions for user: | - |
| Further information: | - |

| SECTION 15. Regulatory information | |
|------------------------------------|--|
| 15.1 | Safety, health and environmental regulations/legislation specific for the substance or mixture |
| | EU regulations |
| | Authorization and/or restrictions of use |
| | Authorizations: - |
| | Restrictions: - |
| | Other EU regulations: EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives |
| | Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline) |
| | National legislation: 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 |
| 15.2 | Chemical safety assessment |
| | None |

| SECTION 16. Other information | |
|-------------------------------|--------------------------|
| 16.1 | Indication of changes: - |

| | | | |
|---------------|---------------------|----------------|-------------|
| Trading name: | HISTANOL 100 | | |
| Product code: | H100-X** | Revision date: | 13 May 2019 |
| | | Version: | |

| | | | |
|-------|---|--|--|
| 16.2 | Abbreviations and acronyms: | PBT | Stable, bioaccumulative and toxic |
| | | vPvB | Strongly stable and strongly bioaccumulative. |
| | | LD ₅₀ | Lethal dose, 50% |
| | | LC ₅₀ | Lethal concentration, 50% |
| | | TCOJ | Specific target organ toxicity - single exposure |
| 16.3. | Key literature references and source of data: | Manufacturer's MSDS file. | |
| 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: | H225 | Highly flammable liquid and vapor. |
| 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> | |

| |
|---|
| ANNEX: Exposure scenario resulting to chemical safety assessment |
| - |

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |


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

| | |
|--|--|
| 1.1. Product identifier | |
| Trade name: | BioClear New |
| Chemical name: | - |
| Catalogue number: | BCN-X** |
| 1.2. Relevant identified uses of the substance or mixture and uses advised against | |
| Uses: | Xylene substitute for tissue processing, deparaffinization and clearing. |
| 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 |
| Telefax: | +385 1 2404039 |
| e-mail of competent person: | msds@biognost.hr |
| National contact: | - |
| 1.4. Emergency telephone numbers | |
| 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: | Warning statements*: |
| Aspir. Tox. 1 | H304 |
| 2.1.2. Additional information | |
| EUH066 | |
| * For full text of Hazard- and EU Hazard-statements: see SECTION 16 | |
| 2.2. Label elements | |
| Product identification: | BioClear New |
| Identification number: | - |
| Authorisation number: | - |

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
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| | |
|---------------------------------------|--|
| Hazard pictograms: |  |
| | GHS08 |
| Signal word: | Danger |
| Hazard statement: | H304 May be fatal if swallowed and enters airways. EUH066 Repeated exposure may cause skin dryness or cracking. |
| Precautionary statements: | P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P331 Do NOT induce vomiting. P370+P378 In case of fire: Use water fog, foam, dry chemical or carbon dioxide (CO ₂) for extinction. P403+P235 Store in a well-ventilated place. Keep cool. |
| Supplemental hazard information (EU): | - |
| 2.3. Other hazards | |
| | - |

| SECTION 3. Composition/information on ingredients | | | | |
|---|-----------------------|-----------------------------|--|--|
| CAS/EC/ Index number | REACH Registration No | Weight % content (or range) | Identification name | Classification according to Regulation (EC) No 1272/2008 (CLP) |
| -/ 920-901-0/ - | 01-2119456810-40 | 100% | Hydrocarbons, C11-C13, isoalkanes, <2% aromatics | Aspir. tox. 1; H304 EUH066 |

| SECTION 4. First aid measures | |
|--|---|
| 4.1. Description of first aid measures | |
| General notes: | If the suggested first aid measures do not prove sufficient, seek medical attention. |
| Following inhalation: | Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation. |

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
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| | |
|------------------------------------|---|
| Following skin contact: | Remove contaminated clothing. Thoroughly wash with water and soap for 15 minutes. |
| Following eye contact: | Rinse the eyes using mild jet of clean water for at least 15 minutes with the eyelids held wide open. Contact a physician if irritation occurs. |
| Following ingestion: | DO NOT induce vomiting. Seek immediate medical attention. |
| Self-protection of the first aider | - |

4.2. Most important symptoms and effects, both acute and delayed

| | |
|-------------------------|---|
| Following inhalation: | Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system. |
| Following skin contact: | Prolonged and/or repeated exposure to low viscosity content may cause skin dryness or cracking. May be irritating to the eyes, nose, throat and lungs. |
| Following eye contact: | Eye irritation may occur during exposure to vapor concentrations above recommended level. |
| Following ingestion: | If swallowing occurs, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately. |

4.3. Indication of any immediate medical attention and special treatment needed

| |
|---|
| - |
|---|

SECTION 5. Firefighting measures

5.1. Extinguishing media

| | |
|---------------------------------|--|
| Suitable extinguishing media: | Water spray, foam, dry powder, CO ₂ |
| Unsuitable extinguishing media: | Straight streams of water |

5.2. Special hazards arising from the substance or mixture

| | |
|--------------------------------|---|
| Hazardous by products of fire: | Smoke, fume, incomplete combustion products, carbon oxydes. |
|--------------------------------|---|

5.3. Advice for firefighters

| |
|---|
| Evacuate the area. Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing). Use water spray to cool fire exposed surfaces and to protect personnel. |
|---|

5.4. Additional information

| |
|---|
| - |
|---|

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |

| | | |
|--------|---|---|
| | Protective equipment: | When disposing of small quantities use protective clothing. When disposing of large quantities use self-contained open-circuit compressed air breathing apparatus or self-contained closed-circuit air breathing apparatus. |
| | Accident prevention methods: | Secure a safety zone, remove all ignition sources, and in case of an accident inform the Emergency service (112) and the manufacturer or sender. Position a prohibition sign with symbols of flame and devices that cause sparks. |
| | Emergency procedures: | Remove or neutralize all factors that may exacerbate the condition, use all allowed means of containing the situation and use recommended means of personal protection. |
| 6.1.2. | For emergency responders: | |
| | | Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing). |
| 6.2. | Environmental precautions: | |
| | | Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater. |
| 6.3. | Methods and materials for containment and cleaning up | |
| 6.3.1. | Bunding, covering of drains; capping procedures: | Sand protective barrier or barriers made of similar materials |
| 6.3.2. | Cleaning up: | Sawdust, sand, mineral adsorbents |
| 6.3.3. | Other information: | Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112). |
| 6.4. | Reference to other sections | |
| | | See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment. |

| | | |
|--|--|--|
| SECTION 7. Handling and storage | | |
| 7.1. | Precautions for safe handling | |
| 7.1.1. | Protection measures | |
| | Measures to prevent fire: | Keep away from sources of ignition and heat. Do not use tools that cause sparks. |
| | 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: | |

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |

| | |
|--|--|
| Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating. Avoid skin contact. | |
| 7.2. Conditions for safe storage, including any incompatibilities | |
| Technical measures and storage conditions: | Keep in a cool and well-ventilated place. Keep away from heat and direct solar radiation. |
| Packaging materials: | Teflon, polypropylene, stainless steel, carbon steel. |
| Requirements for storage rooms and vessels: | Keep away from food and drink. Keep the containers tightly closed. Store in a cool, well-ventilated area. |
| 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: | Suitable materials and coating are teflon, polypropylene, polyethylene, stainless steel, carbon steel. Unsuitable materials and coatings include ethylene propylene diene monomer (EPDM), natural rubber, polystyrene, butyl rubber. |
| 7.3. Specific end use(s) | |
| Recommendations: | This product attracts static electricity that may cause electrical sparking (ignition source) that may ignite flammable vapors of the liquid. The liquid is usually an isolator if its conductivity level is under 100 pS/m. It is considered a semiconductor that attracts static electricity if its conductivity level is less than 10,000 pS/m. Regardless of the type of the liquid (isolator or semiconductor), precautions are the same. Numerous factors, such as the liquid temperature, contaminants, antistatic additives and filtration may severely influence the liquid conductivity. |
| 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 ³ | |
| Hydrocarbons, C11-C13, isoalkanes, <2% aromatics | - | 171* | 1200* | No information available |
| * Source - material safety data sheet provided by the raw materials supplier | | | | |
| Substance: | - | | | |
| EC No: | - | CAS No: | - | |
| DNEL | | | | |

| | | | | |
|---------------|---------------------|----------------------|-------------|------------|
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| Industrial | | | | |
|--------------------|--------------------|--------------------|--------------------|--------------------|
| Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: |
| Oral | - | - | - | - |
| Inhalation | - | - | - | - |
| Dermal | - | - | - | - |

Critical physical parameters: solubility, flammability, corrosivity: -

| Consumer | | | | |
|--------------------|--------------------|--------------------|--------------------|--------------------|
| Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: |
| 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 |
| Air | No information available |

| | | |
|--------|--|--|
| 8.2. | Exposure controls | |
| 8.2.1. | Appropriate engineering controls | |
| | Substance/mixture related measures to prevent exposure during identified uses: | Do not eat, drink or smoke in the workspace. Use personal protective equipment. Wash hands after handling the product and before eating and/or drinking. |
| | Structural measures to prevent exposure: | Adequate ventilation should be provided so that exposure limits are not exceeded. Use explosion-proof ventilation equipment. |
| | Organisational measures to prevent exposure: | Organization of work in order to reduce other worker's influence during work process. |
| | Technical measures to prevent exposure: | See Section 7.2 |
| 8.2.2. | Personal protection equipment: | |

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
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| | | |
|----------|---|---|
| 8.2.2.1. | Eye and face protection: | Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air. |
| 8.2.2.2. | Skin protection | |
| | Hand protection: | In case prolonged or repeated contact with the product, use nitril rubber protective gloves (EN 374). |
| | Other skin protection: | Wear full protective suit that protects from chemicals (EN 340) and shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material. |
| 8.2.2.3. | Respiratory protection: | If the concentration level exceeds the GVI values (or because of inadequate ventilation), use full gas mask (EN 136) equipped with a recommended filter type A. |
| 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

| | | | |
|--|--|----------------------------|--------------------------|
| 9.1. Information on basic physical and chemical properties | | | |
| | | Value | Method |
| | Physical state: | liquid | No information available |
| | Colour: | colourless | No information available |
| | Odour: | faint | No information available |
| | Odour threshold; | No information available | No information available |
| | pH: | No information available | No information available |
| | Melting point / freezing point; | No information available | No information available |
| | Initial boiling point and boiling range: | 170 - 250 °C | No information available |
| | Flash point: | 62 °C | No information available |
| | Evaporation rate: | 0,05 (n-Butyl acetate = 1) | No information available |
| | Flammability (solid, gas): | No information available | No information available |

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |

| | | |
|---|--|--------------------------|
| Upper/lower flammability or explosive limits: | lower: 0.6 upper: 7.0 | No information available |
| Vapour pressure: | 0.04 kPa (0.3 mm Hg) at 20 °C | No information available |
| Vapour density: | > 1 at 101 kPa (Air = 1) | No information available |
| Relative density | 0.731 – 0.851 (15 °C) | No information available |
| Bulk density: | No information available | No information available |
| Solubility(ies): | Negligible | No information available |
| Partition coefficient: n-octanol/water (log Kow): | No information available | No information available |
| Auto-ignition temperature: | > 200 °C | No information available |
| Decomposition temperature: | No information available | No information available |
| Viscosity: | 1.3 cSt (1.3 mm ² /sec) at 20 °C 2.5 cSt (2.5 mm ² /sec) at 20 °C | No information available |
| Explosive properties: | No information available | No information available |
| Oxidising properties: | No information available | No information available |
| 9.2. | Other information | |
| | - | |

| SECTION 10.: Stability and reactivity | | |
|--|-------------------------------------|---|
| 10.1. | Reactivity: | No information available |
| 10.2. | Chemical stability: | The product is chemically stable under standard ambient conditions of storing and using (room temperature). |
| 10.3. | Possibility of hazardous reactions: | Hazardous polymerization will not occur. |
| 10.4. | Conditions to avoid: | Open flames and high energy ignition sources. |
| 10.5. | Incompatible materials: | Strong oxidants. |
| 10.6. | Hazardous decomposition products: | Product decomposition will not occur at ambient temperature. |

| SECTION 11. Toxicological information | | | | | |
|--|--------------------------|---------|--|---------------|-------------------|
| 11.1. Information on toxicological effects | | | | | |
| Acute toxicity: | | | | | |
| Route of exposure: | Method | Species | Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture} | Exposure time | Results |
| Oral: | No information available | rat | LD ₅₀ > 5000 mg/kg | - | Minimal toxicity. |
| Dermal: | No information available | rabbit | LD ₅₀ > 5000 mg/kg | - | Minimal toxicity. |

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |

| | | | | | |
|-------------|--------------------------|-----|-------------------------------|-----|-------------------|
| Inhalation: | No information available | rat | LC ₅₀ > 5000 mg/kg | 4 h | Minimal toxicity. |
|-------------|--------------------------|-----|-------------------------------|-----|-------------------|

Specific target organ toxicity - single exposure (STOT-SE):

| | Specific effects | Target organ | Note |
|-------------|--------------------------|--------------------------|------|
| Oral: | No information available | No information available | - |
| Dermal: | No information available | No information available | - |
| Inhalation: | No information available | No information available | - |

Aspiration hazard: Insignificant danger at normal handling temperature.

Irritation and corrosion

| | Exposure time | Species | Evaluation | Method | Note |
|-------------------------------|--------------------------|---------|-----------------|---------------|------|
| Skin corrosion/irritation | No information available | rabbit | Not irritating. | OECD | - |
| Serious eye damage/irritation | No information available | rabbit | Not irritating. | not specified | - |

Sensitization

| | |
|----------------------------|--|
| Skin sensitization: | Not expected to be a skin sensitizer. |
| Respiratory sensitization: | Not expected to be a respiratory sensitizer. |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|----------------------|---|
| Oral exposure: | If swallowing occurs, aspiration of the vomit may also occur and cause chemical pneumonitis or pulmonary oedema. |
| Dermal exposure: | Prolonged and/or repeated exposure to low viscosity content may cause irritation and dermatitis, skin drying or cracking. |
| Inhalation exposure: | Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system. |
| Eye exposure: | Eye irritation may occur during exposure to vapor concentrations above recommended level. |

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 | - |

| | | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|--|
| Trade name: | BIOCLEAR NEW | | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 | |

| | | | | | | |
|-----------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| 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 | - |
| 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: | No carcinogenicity studies were made, but since the product is not mutagenic and causes a minimal level of toxicity, it can be assumed that chronic exposure will not cause tumors. |
|------------------|---|

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |

| | |
|---|--------------------------|
| Mutagenicity <i>in-vitro</i> : | No information available |
| Genotoxicity: | No information available |
| Mutagenicity <i>in-vivo</i> : | No information available |
| Germ cell mutagenicity : | No information available |
| Reproductive toxicity: | No information available |
| Summary of evaluation of the CMR properties; : | No information available |
| 11.2. Practical experiences: | |
| Classification observations: | No information available |
| Other observations: | No information available |
| 11.3. General notes: | |
| Vapour concentration above recommended exposure levels are irritating to the eyes and the respiratory tract, may cause headaches and dizziness, are anesthetic may have other central nervous system effects. Prolonged and/or repeated skin contact with low viscosity materials may defat skin resulting in possible irritation and dermatitis. Small amounts of liquid aspirated into the lungs during ingestion or from vomiting may cause chemical pneumonitis or pulmonary edema. | |

| SECTION 12. Ecological information | | | | | | |
|---|------------------|---------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 12.1. Toxicity | | | | | | |
| Acute (short-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
| Fish: | LC ₅₀ | 96 hours | No information available | No information available | - | - |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | - | - |
| Algae/aquatic plants: | IC ₅₀ | 72 hours | No information available | No information available | - | - |
| Other organisms: | - | - | - | - | - | - |
| Chronic (long-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
| Fish: | LC ₅₀ | 96 hours | No information available | No information available | No information available | No information available |

| | | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|--|
| Trade name: | BIOCLEAR NEW | | | | | |
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| | | | | | | |
|-----------------------|------------------|----------|--------------------------|--------------------------|--------------------------|--------------------------|
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | No information available |
| Algae/aquatic plants: | IC ₅₀ | 72 hours | No information available | 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 | No information available | No information available |
| | | | | | | |

Bioconcentration Factor (BCF)

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

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
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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 ₅₀ | No information available | No information available | No information available | No information available | Not expected. |
| Chronic toxicity on crustacea (Daphnia) | EC ₅₀ | No information available | No information available | No information available | No information available | Not expected. |

12.4. Mobility in soil

| | | | | | | |
|--|--------------------------|--------------------------|--------------------------|------|--|--|
| Known or predicted distribution in environmental compartments: | | | | | | |
| 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 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

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |

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

| | |
|-------|-----------------------|
| 12.6. | Other adverse effects |
|-------|-----------------------|

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

SECTION 13. Disposal considerations

| | |
|-------|-------------------------|
| 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. 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.

| | |
|---------|--|
| 13.1.2. | Waste codes/waste designations according to Law: |
|---------|--|

European Waste Code: 08 XX XX
 These codes are assigned based upon the most common uses for this material and may not reflect contaminants resulting from actual use. Waste producers need to assess the actual process used when generating the waste and its contaminants in order to assign the proper waste disposal code(s).

| | |
|---------|--|
| 13.1.3. | Waste codes/waste designations according to Law: |
|---------|--|

Incinerating the product at high temperatures is recommended in order to avoid incomplete combustion products.

| | |
|---------|---|
| 13.1.4. | Sewage disposal – relevant information: |
|---------|---|

Waste must not be disposed of into the sewage system.

| | |
|---------|---------------------------------|
| 13.1.5. | Other disposal recommendations: |
|---------|---------------------------------|

Empty Container Warning: Empty containers may contain residue and can be dangerous. Do not attempt to refill or clean containers without proper instructions. Empty drums should be completely drained and safely stored until appropriately reconditioned or disposed. Empty containers should be taken for recycling, recovery or disposal through suitably qualified or licensed contractor and in accordance with governmental regulations. Do not pressurise, cut, weld, braze, solder, drill, grind or expose such containers to heat, flame, sparks, static electricity or other sources of ignition. They may explode and cause injury or death.

| | |
|---------|--------------------------------|
| 13.1.6. | Relevant Community provisions: |
|---------|--------------------------------|

-

SECTION 14. Transport information

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |

| | |
|--|---------------------------------------|
| Transporting/shipment by road (ADR) | |
| UN number: | Not subject to transport regulations. |
| UN proper shipping name: | - |
| Transport hazard class(es): | - |
| Packing group: | - |
| Environmental hazards: | - |
| 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: | - |
| Environmental hazards: | - |
| Special precautions for user: | - |
| Transporting/shipment by inland waterways (ADN) | |
| UN number: | Not subject to transport regulations. |
| UN proper shipping name: | - |
| Transport hazard class(es): | - |
| Packing group: | - |
| Environmental hazards: | - |
| 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: | - |
| Environmental hazards: | - |
| Special precautions for user: | - |
| Transport in bulk according to Annex II of MARPOL73/78 and the IBC code: | - |
| 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: | - |
| Environmental hazards: | - |

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |

| | |
|-------------------------------|---|
| Special precautions for user: | - |
| Further information: | - |

SECTION 15. Regulatory information

| | | |
|-------|--|---|
| 15.1. | Safety, health and environmental regulations/legislation specific for the substance or mixture | |
| | EU regulations | |
| | Authorisations and/or restrictions on use | |
| | Authorisations: | - |
| | Restrictions: | - |
| | Other EU regulations: | <p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</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> |
| 15.2. | Chemical safety assessment | |
| | None | |

SECTION 16. Other information

| | | |
|-------|------------------------|---|
| 16.1. | Indication of changes: | - |
|-------|------------------------|---|

| | | | | | |
|---------------|---------------------|----------------------|-------------|----------|---|
| Trade name: | BIOCLEAR NEW | | | | |
| Product code: | BCN-X** | Date of compilation: | 15 Feb 2019 | Version: | 5 |

| | | | | |
|-------|---|--------------|--|--|
| 16.2. | Abbreviations and acronyms: | and | PBT | Stable, bioaccumulative and toxic |
| | | | vPvB | Strongly stable and strongly bioaccumulative. |
| | | | LD ₅₀ | Lethal dose, 50% |
| | | | LC ₅₀ | Lethal concentration, 50% |
| | | | STOT-SE | Specific target organ toxicity – single exposure |
| 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: | 304 (EUH066) | May be fatal if swallowed and enters airways. Repeated exposure may cause skin dryness or cracking. | |
| 16.6. | Training advice: | | - | |
| 16.7. | Further information: | | ** "X" in the product code marks different volumes (different packaging of the product) 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. | |


| |
|---|
| ANNEX: Exposure scenario resulting to Chemical safety assessment |
| - |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
| Trade name: | BIOMOUNT NEW LOW | | | | |
| Product code: | BMNL-X** | Date of compilation: | 04 June 2019 | Version: | 3 |

| SECTION 1: Identification of the substance/mixture and of the company/undertaking | |
|---|--|
| 1.1. Product identifier | |
| Trade name: | BIOMOUNT NEW LOW |
| Chemical name: | - |
| Catalogue number: | BMNL-X** |
| 1.2. Relevant identified uses of the substance or mixture and uses advised against | |
| Uses: | For covering microscope sections and mounting covering glasses. |
| 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 |
| Telefax: | +385 1 2404039 |
| e-mail of competent person: | msds@biognost.hr |
| National contact: | - |
| 1.4. Emergency telephone numbers | |
| 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: | Warning statements*: |
| Aspir. Tox. 1 | H304 |
| 2.1.2. Additional information | |
| EUH066 | |
| * For full text of Hazard- and EU Hazard-statements: see SECTION 16 | |
| 2.2. Label elements | |
| Product identification: | BIOMOUNT NEW LOW |
| Identification number: | - |
| Authorisation number: | - |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
| Trade name: | BIOMOUNT NEW LOW | | | | |
| Product code: | BMNL-X** | Date of compilation: | 04 June 2019 | Version: | 3 |

| | |
|---------------------------------------|---|
| Hazard pictograms: |  |
| | GHS08 |
| Signal word: | Danger |
| Hazard statement: | H304 May be fatal if swallowed and enters airways. EUH066 Repeated exposure may cause skin dryness or cracking. |
| Precautionary statements: | P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P331 Do NOT induce vomiting. P403+P235 Store in a well-ventilated place. Keep cool. |
| Supplemental hazard information (EU): | - |
| 2.3. Other hazards | - |

| SECTION 3. Composition/information on ingredients | | | | |
|---|-----------------------|-----------------------------|--|--|
| CAS/EC/ Index number | REACH Registration No | Weight % content (or range) | Identification name | Classification according to Regulation (EC) No 1272/2008 (CLP) |
| -/ 920-901-0/ - | 01-2119456810-40 | 60-80% | Hydrocarbons, C11-C13, isoalkanes, <2% aromatics | Aspir. tox. 1; H304 EUH066 |

| SECTION 4. First aid measures | |
|-------------------------------|---|
| 4.1. | Description of first aid measures |
| General notes: | If the suggested first aid measures do not prove sufficient, seek medical attention. |
| Following inhalation: | Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation. |
| Following skin contact: | Remove contaminated clothing. Thoroughly wash with water and soap for 15 minutes. |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
| Trade name: | BIOMOUNT NEW LOW | | | | |
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| | |
|------------------------------------|---|
| Following eye contact: | Rinse the eyes using mild jet of clean water for at least 15 minutes with the eyelids held wide open. Contact a physician if irritation occurs. |
| Following ingestion: | DO NOT induce vomiting. Seek immediate medical attention. |
| Self-protection of the first aider | - |

4.2. Most important symptoms and effects, both acute and delayed

| | |
|-------------------------|---|
| Following inhalation: | Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system. |
| Following skin contact: | Prolonged and/or repeated exposure to low viscosity content may cause skin dryness or cracking. May be irritating to the eyes, nose, throat and lungs. |
| Following eye contact: | Eye irritation may occur during exposure to vapor concentrations above recommended level. |
| Following ingestion: | If swallowing occurs, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately. |

4.3. Indication of any immediate medical attention and special treatment needed

| |
|---|
| - |
|---|

SECTION 5. Firefighting measures

5.1. Extinguishing media

| | |
|---------------------------------|--|
| Suitable extinguishing media: | Water spray, foam, dry powder, CO ₂ |
| Unsuitable extinguishing media: | Straight streams of water |

5.2. Special hazards arising from the substance or mixture

| | |
|--------------------------------|---|
| Hazardous by products of fire: | Smoke, fume, incomplete combustion products, carbon oxides. |
|--------------------------------|---|

5.3. Advice for firefighters

| |
|---|
| Evacuate the area. Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing). Use water spray to cool fire exposed surfaces and to protect personnel. |
|---|

5.4. Additional information

| |
|---|
| - |
|---|

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

| | |
|-----------------------|---|
| Protective equipment: | When disposing of small quantities use protective clothing. When disposing of large quantities use self-contained open-circuit compressed air breathing apparatus or self-contained closed-circuit air breathing apparatus. |
|-----------------------|---|

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
| Trade name: | BIOMOUNT NEW LOW | | | | |
| Product code: | BMNL-X** | Date of compilation: | 04 June 2019 | Version: | 3 |

| | | |
|--------|---|---|
| | Accident prevention methods: | Secure a safety zone, remove all ignition sources, and in case of an accident inform the Emergency service (112) and the manufacturer or sender. Position a prohibition sign with symbols of flame and devices that cause sparks. |
| | Emergency procedures: | Remove or neutralize all factors that may exacerbate the condition, use all allowed means of containing the situation and use recommended means of personal protection. |
| 6.1.2. | For emergency responders: | |
| | Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing). | |
| 6.2. | Environmental precautions: | |
| | Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater. | |
| 6.3. | Methods and materials for containment and cleaning up | |
| 6.3.1. | Bunding, covering of drains; capping procedures: | Sand protective barrier or barriers made of similar materials |
| 6.3.2. | Cleaning up: | Sawdust, sand, mineral adsorbents |
| 6.3.3. | Other information: | Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112). |
| 6.4. | Reference to other sections | |
| | See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment. | |

| | | |
|--|--|--|
| SECTION 7. Handling and storage | | |
| 7.1. | Precautions for safe handling | |
| 7.1.1. | Protection measures | |
| | Measures to prevent fire: | Keep away from sources of ignition and heat. Do not use tools that cause sparks. |
| | 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. Avoid skin contact. | |
| 7.2. | Conditions for safe storage, including any incompatibilities | |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
| Trade name: | BIOMOUNT NEW LOW | | | | |
| Product code: | BMNL-X** | Date of compilation: | 04 June 2019 | Version: | 3 |

| | |
|---|---|
| Technical measures and storage conditions: | Keep in a cool and well-ventilated place. Keep away from heat and direct solar radiation. |
| Packaging materials: | Teflon, polypropylene, stainless steel, carbon steel. |
| Requirements for storage rooms and vessels: | Keep away from food and drink. Keep the containers tightly closed. Store in a cool, well-ventilated area. |
| 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: | Suitable materials and coating are teflon, polypropylene, polyethylene, stainless steel, carbon steel. Unsuitable materials and coatings include ethylene propylene diene monomer (EPDM), natural rubber, polystyrene, butyl rubber. |

| | |
|---------------------------------------|--|
| 7.3. Specific end use(s) | |
| Recommendations: | This product attracts static electricity that may cause electrical sparking (ignition source) that may ignite flammable vapors of the liquid. The liquid is usually an isolator if its conductivity level is under 100 pS/m. It is considered a semiconductor that attracts static electricity if its conductivity level is less than 10,000 pS/m. Regardless of the type of the liquid (isolator or semiconductor), precautions are the same. Numerous factors, such as the liquid temperature, contaminants, antistatic additives and filtration may severely influence the liquid conductivity. |
| 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 ³ | |
| Hydrocarbons, C11-C13, isoalkanes, <2% aromatics | - | 171* | 1200* | No information available |

* Source - material safety data sheet provided by the raw materials supplier

| | |
|------------|---|
| Substance: | - |
| EC No: | - |
| CAS No: | - |

DNEL

Industrial

| | | | | |
|--------------------|--------------------|--------------------|--------------------|--------------------|
| Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: |
|--------------------|--------------------|--------------------|--------------------|--------------------|

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
| Trade name: | BIOMOUNT NEW LOW | | | | |
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| | | | | |
|------------|---|---|---|---|
| Oral | - | - | - | - |
| Inhalation | - | - | - | - |
| Dermal | - | - | - | - |

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

| Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: |
|--------------------|--------------------|--------------------|--------------------|--------------------|
| 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 |
| Air | No information available |

8.2. Exposure controls

8.2.1. Appropriate engineering controls

| | |
|--|--|
| Substance/mixture related measures to prevent exposure during identified uses: | Do not eat, drink or smoke in the workspace. Use personal protective equipment. Wash hands after handling the product and before eating and/or drinking. |
| Structural measures to prevent exposure: | Adequate ventilation should be provided so that exposure limits are not exceeded. Use explosion-proff ventilation equipment. |
| Organisational measures to prevent exposure: | Organization of work in order to reduce other worker's influence during work process. |
| Technical measures to prevent exposure: | See Section 7.2 |

8.2.2. Personal protection equipment:

| | |
|-----------------------------------|--|
| 8.2.2.1. Eye and face protection: | Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air. |
| 8.2.2.2. Skin protection | |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
| Trade name: | BIOMOUNT NEW LOW | | | | |
| Product code: | BMNL-X** | Date of compilation: | 04 June 2019 | Version: | 3 |

| | | |
|----------|---|---|
| | Hand protection: | In case prolonged or repeated contact with the product, use nitril rubber protective gloves (EN 374). |
| | Other skin protection: | Wear full protective suit that protects from chemicals (EN 340) and shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material. |
| 8.2.2.3. | Respiratory protection: | If the concentration level exceeds the GVI values (or because of inadequate ventilation), use full gas mask (EN 136) equipped with a recommended filter type A. |
| 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

| | | | |
|------|--|--------------------------|--------------------------|
| 9.1. | Information on basic physical and chemical properties | | |
| | | Value | Method |
| | Physical state: | liquid | No information available |
| | Colour: | colourless | No information available |
| | Odour: | faint | No information available |
| | Odour threshold; | No information available | No information available |
| | pH: | No information available | No information available |
| | Melting point / freezing point; | No information available | No information available |
| | Initial boiling point and boiling range: | 170 - 250 °C | No information available |
| | Flash point: | 62 °C | No information available |
| | Evaporation rate: | No information available | No information available |
| | Flammability (solid, gas): | No information available | No information available |
| | Upper/lower flammability or explosive limits: | No information available | No information available |
| | Vapour pressure: | No information available | No information available |
| | Vapour density: | No information available | No information available |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
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| | | | |
|------|---|--------------------------|--------------------------|
| | Relative density | No information available | No information available |
| | Bulk density: | No information available | No information available |
| | Solubility(ies): | Negligible | No information available |
| | Partition coefficient: n-octanol/water (log Kow): | No information available | No information available |
| | Auto-ignition temperature: | > 200 °C | No information available |
| | Decomposition temperature: | No information available | No information available |
| | Viscosity: | No information available | No information available |
| | Explosive properties: | No information available | No information available |
| | Oxidising properties: | No information available | No information available |
| 9.2. | Other information | | |
| | - | | |

| SECTION 10.: Stability and reactivity | | |
|---------------------------------------|-------------------------------------|---|
| 10.1. | Reactivity: | No information available |
| 10.2. | Chemical stability: | The product is chemically stable under standard ambient conditions of storing and using (room temperature). |
| 10.3. | Possibility of hazardous reactions: | Hazardous polymerization will not occur. |
| 10.4. | Conditions to avoid: | Open flames and high energy ignition sources. |
| 10.5. | Incompatible materials: | Strong oxidants. |
| 10.6. | Hazardous decomposition products: | Product decomposition will not occur at ambient temperature. |

| SECTION 11. Toxicological information | | | | | |
|---|--------------------------|---------|--|---------------|---------|
| 11.1. Information on toxicological effects | | | | | |
| Acute toxicity: | | | | | |
| Route of exposure: | Method | Species | Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture} | Exposure time | Results |
| Oral: | No information available | rat | LD ₅₀ > 5000 mg/kg | - | - |
| Dermal: | No information available | rabbit | LD ₅₀ > 5000 mg/kg | - | - |
| Inhalation: | No information available | rat | LC ₅₀ > 5000 mg/kg | 4 h | - |
| Specific target organ toxicity - single exposure (STOT-SE): | | | | | |
| | Specific effects | | Target organ | | Note |
| Oral: | No information available | | No information available | | - |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
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| | | | |
|-------------|--------------------------|--------------------------|---|
| Dermal: | No information available | No information available | - |
| Inhalation: | No information available | No information available | - |

| | |
|--------------------|--|
| Aspiration hazard: | Insignificant danger at normal handling temperature. |
|--------------------|--|

| |
|---------------------------------|
| Irritation and corrosion |
|---------------------------------|

| | Exposure time | Species | Evaluation | Method | Note |
|-------------------------------|--------------------------|---------|-----------------|---------------|------|
| Skin corrosion/irritation | No information available | rabbit | Not irritating. | OECD | - |
| Serious eye damage/irritation | No information available | rabbit | Not irritating. | not specified | - |

| |
|----------------------|
| Sensitization |
|----------------------|

| | |
|----------------------------|--|
| Skin sensitization: | Not expected to be a skin sensitizer. |
| Respiratory sensitization: | Not expected to be a respiratory sensitizer. |

| |
|---|
| Symptoms related to the physical, chemical and toxicological characteristics |
|---|

| | |
|----------------------|---|
| Oral exposure: | If swallowing occurs, aspiration of the vomit may also occur and cause chemical pneumonitis or pulmonary oedema. |
| Dermal exposure: | Prolonged and/or repeated exposure to low viscosity content may cause irritation and dermatitis, skin drying or cracking. |
| Inhalation exposure: | Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system. |
| Eye exposure: | Eye irritation may occur during exposure to vapor concentrations above recommended level. |

| |
|---|
| 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 | - |

| | | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|--|
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| | | | | | | |
|-----------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| 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 | - |
| 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: | No carcinogenicity studies were made, but since the product is not mutagenic and causes a minimal level of toxicity, it can be assumed that chronic exposure will not cause tumors. |
| Mutagenicity <i>in-vitro</i> : | No information available |
| Genotoxicity: | No information available |
| Mutagenicity <i>in-vivo</i> : | No information available |
| Germ cell mutagenicity : | No information available |
| Reproductive toxicity: | No information available |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
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| | | |
|--|--------------------------|--------------------------|
| Summary of evaluation of the CMR properties; : | | No information available |
| 11.2. Practical experiences: | | |
| Classification observations: | No information available | |
| Other observations: | No information available | |
| 11.3. General notes: | | |
| - | | |

| SECTION 12. Ecological information | | | | | | |
|--|------------------|---------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 12.1. Toxicity | | | | | | |
| Acute (short-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
| Fish: | LC ₅₀ | 96 hours | No information available | No information available | - | - |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | - | - |
| Algae/aquatic plants: | IC ₅₀ | 72 hours | No information available | No information available | - | - |
| Other organisms: | - | - | - | - | - | - |
| Chronic (long-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
| Fish: | LC ₅₀ | 96 hours | No information available | No information available | No information available | No information available |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | No information available |
| Algae/aquatic plants: | IC ₅₀ | 72 hours | No information available | No information available | No information available | No information available |
| Other organisms: | - | - | - | - | - | - |
| 12.2. Persistence and degradability | | | | | | |
| Abiotic degradation | | | | | | |

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

Bioconcentration Factor (BCF)

| Value | Species | Method | Evaluation | Note |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 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 ₅₀ | No information available | No information available | No information available | No information available | Not expected. |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
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| | | | | | | |
|---|------------------|--------------------------|--------------------------|--------------------------|--------------------------|---------------|
| Chronic toxicity on crustacea (Daphnia) | EC ₅₀ | No information available | No information available | No information available | No information available | Not expected. |
|---|------------------|--------------------------|--------------------------|--------------------------|--------------------------|---------------|

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:

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 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

12.6. Other adverse effects

No information available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

| | | | | | |
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Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection. 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.

13.1.2. Waste codes/waste designations according to Law:

European Waste Code: 08 XX XX
 These codes are assigned based upon the most common uses for this material and may not reflect contaminants resulting from actual use. Waste producers need to assess the actual process used when generating the waste and its contaminants in order to assign the proper waste disposal code(s).

13.1.3. Waste codes/waste designations according to Law:

Incinerating the product at high temperatures is recommended in order to avoid incomplete combustion products.

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

Empty Container Warning: Empty containers may contain residue and can be dangerous. Do not attempt to refill or clean containers without proper instructions. Empty drums should be completely drained and safely stored until appropriately reconditioned or disposed. Empty containers should be taken for recycling, recovery or disposal through suitably qualified or licensed contractor and in accordance with governmental regulations. Do not pressurise, cut, weld, braze, solder, drill, grind or expose such containers to heat, flame, sparks, static electricity or other sources of ignition. They may explode and cause injury or death.

13.1.6. Relevant Community provisions:

-

SECTION 14. Transport information

Transporting/shipment by road (ADR)

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

Transporting/shipment by rail (RID)

| | |
|------------|---------------------------------------|
| UN number: | Not subject to transport regulations. |
|------------|---------------------------------------|

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
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| | |
|-------------------------------|---|
| UN proper shipping name: | - |
| Transport hazard class(es): | - |
| Packing group: | - |
| Environmental hazards: | - |
| Special precautions for user: | - |

| | |
|---|---------------------------------------|
| Transporting/shipment by inland waterways (ADN) | |
| UN number: | Not subject to transport regulations. |
| UN proper shipping name: | - |
| Transport hazard class(es): | - |
| Packing group: | - |
| Environmental hazards: | - |
| 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: | - |
| Environmental hazards: | - |
| Special precautions for user: | - |
| Transport in bulk according to Annex II of MARPOL73/78 and the IBC code: | - |

| | |
|---|---------------------------------------|
| 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: | - |
| Environmental hazards: | - |
| Special precautions for user: | - |

| | |
|----------------------|---|
| Further information: | - |
|----------------------|---|

| SECTION 15. Regulatory information | |
|---|--|
| 15.1. | Safety, health and environmental regulations/legislation specific for the substance or mixture |
| | EU regulations |
| | Authorisations and/or restrictions on use |
| | Authorisations: - |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
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| | |
|--|---|
| Restrictions: | - |
| Other EU regulations: | <p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</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> |
| 15.2. Chemical safety assessment | |
| | None |

| SECTION 16. Other information | | | | | | | | | | | |
|---|--|-----|-----------------------------------|------|---|------------------|------------------|------------------|---------------------------|---------|--|
| 16.1. Indication of changes: | - | | | | | | | | | | |
| 16.2. Abbreviations and acronyms: | <table> <tr> <td>PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td>LD₅₀</td> <td>Lethal dose, 50%</td> </tr> <tr> <td>LC₅₀</td> <td>Lethal concentration, 50%</td> </tr> <tr> <td>STOT-SE</td> <td>Specific target organ toxicity – single exposure</td> </tr> </table> | PBT | Stable, bioaccumulative and toxic | vPvB | Strongly stable and strongly bioaccumulative. | LD ₅₀ | Lethal dose, 50% | LC ₅₀ | Lethal concentration, 50% | STOT-SE | Specific target organ toxicity – single exposure |
| PBT | Stable, bioaccumulative and toxic | | | | | | | | | | |
| vPvB | Strongly stable and strongly bioaccumulative. | | | | | | | | | | |
| LD ₅₀ | Lethal dose, 50% | | | | | | | | | | |
| LC ₅₀ | Lethal concentration, 50% | | | | | | | | | | |
| STOT-SE | Specific target organ toxicity – single exposure | | | | | | | | | | |
| 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: 304 (EUH066) | <p>May be fatal if swallowed and enters airways.</p> <p>Repeated exposure may cause skin dryness or cracking.</p> | | | | | | | | | | |

| | | | | | |
|---------------|-------------------------|----------------------|--------------|----------|---|
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| | | |
|-------|----------------------|---|
| 16.6. | Training advice: | - |
| 16.7. | Further information: | <p>** "X" in the product code marks different volumes (different packaging 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> |

| | |
|---|--|
| ANNEX: Exposure scenario resulting to Chemical safety assessment | |
| - | |