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|---------------|-------------------|----------------------|------------------|----------|---|
| Trade name: | IMMUNOFORM | | | | |
| Product code: | IMF-X** | Date of compilation: | 21 December 2022 | Version: | 3 |



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

| | | |
|------|---|--|
| 1.1. | Product identifier | |
| | Trade name: | IMMUNOFORM |
| | Chemical name: | - |
| | Catalogue number: | IMF-X** |
| 1.2. | Relevant identified uses of the substance or mixture and uses advised against | |
| | Uses: | Fixative for use in histology and immunohistochemistry. |
| | Uses advised against: | Only the identified uses are advised. |
| | Reasons 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*: |
| | Skin Sens. 1 | H317 |
| | STOT SE 3 | H335 |
| | Muta. 2 | H341 |
| | Carc. 1B | H350 |
| 2.1.2. | Additional information | |
| | - | |
| *For full text of Hazard- and EU Hazard-statements: see Section 16. | | |
| 2.2. | Label elements | |
| | Product identification: | IMMUNOFORM |
| | Identification number: | - |

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| Authorisation number: | - |
| Hazard pictograms: |   GHS08 GHS07 |
| Signal word: | Danger |
| Hazard statement: | H317 May cause an allergic skin reaction. H335 May cause respiratory irritation. H341 Suspected of causing genetic defects. H350 May cause cancer. |
| Precautionary statement: | P280 Wear protective gloves/protective clothing/eye/protection/face protection. P302 + P352 IF ON SKIN: Wash with plenty of water. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312 Call a POISON CENTER/ doctor if you feel unwell. P308+P313 IF exposed or concerned: Get medical advice/attention. |
| Supplemental hazard information (EU): | - |
| 2.3. Other hazards | |
| This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | |

| 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) |
| 30525-89-4/ 608-494-5/ - | - | 3 – 4 % | paraformaldehyde | Acute Tox. 4; H302 Skin Irr. 2; H315 Skin Sens. 1; H317 Eye Dam. 1; H318 Acute Tox. 4; H332 STOT SE 3; H335 Muta. 2; H341 Carc. 1B; H350 |

| SECTION 4. First aid measures | |
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| 4.1. Description of first aid measures | |
| General notes: | If the suggested first aid measures do not prove sufficient, seek medical attention. |

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| 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 using sterile gauze. 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. |
| Following ingestion: | Rinse the oral cavity, drink 1-2 glasses of water. Do not induce vomiting. 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

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|-------------------------|---|
| Following inhalation: | Depending on concentration and exposure time, irritation of the mucous membrane of the nose/throat may occur (burning sensation, urge to sneeze, runny nose). High concentration levels may cause difficult breathing, coughing, chest tightness, headache, pneumonia and pulmonary edema. |
| Following skin contact: | Depending on concentration and exposure time, redness accompanied by sensation of stinging and pain may occur, defatting, skin cracking, rash, swelling, burns, blisters and delayed onset of inflammations. |
| Following eye contact: | Depending on concentration and exposure time, mucosa stinging, lacrimation, redness and pain may occur, as well as bleeding, delayed onset of inflammations and permanent eyesight damage. |
| Following ingestion: | Depending on concentration and exposure time, stinging and possible damage to the mucous membrane of the digestive tract is possible, as well as abdominal pain, nausea, vomiting (bloody vomit is possible), vertigo, headache, eyesight disorders and permanent blindness due to optical nerve damage, loss of consciousness. |

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

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SECTION 5. Firefighting measures

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| 5.1. Extinguishing media | |
| Suitable extinguishing media: | water spray or alcohol-resistant foam, dry powder, CO ₂ |
| Unsuitable extinguishing media: | No information available |
| 5.2. Special hazards arising from the substance or mixture | |
| Hazardous by products of fire: | Possible liberation of toxic carbon monoxide and formaldehyde gases due to thermal decomposition (increased temperature). Explosive mixtures of formaldehyde vapors and air also present danger. |

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| 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, in order to prevent explosion. |
| 5.4. | Additional information |
| | Remove sources of heat and ignition. 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. Remove all sources of sparks and ignition. Do not smoke. |
| | 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 materials 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: Do not use incompatible materials (see Section 10). |
| 6.4. | Reference to other sections |
| | - |

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| SECTION 7. Handling and storage | |
| 7.1. | Precautions for safe handling |
| 7.1.1. | Protection measures |

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| | Measures to prevent fire: | Use in well ventilated storage rooms. Keep away from sources of heat and ignition. Carry out measures for preventing static electricity. |
| | Measures to prevent aerosol and dust formation: | 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 at temperatures ranging from 15 to 25 °C. |
| | Containers materials: | Manufacturer's original packaging. |
| | Requirements for storage and containers: | 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. |
| | Other 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 | |
| - | - | - | - | - |
| Substance: | - | | | |
| EC No: | - | CAS No.: | - | |
| DNEL | | | | |
| Industrial | | | | |

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| 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 |
| Fresh water sediments | No information available |
| Salt water | No information available |
| Salt water 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: | 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 (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. |
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| 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 EN374. Full contact: Material: Nitrile rubber Minimum layer thickness: 0,11 mm Break through time: 480 min Splash contact: Material: Nitrile rubber Minimum layer thickness: 0,11 mm Break through time: 480 min |
| | Other skin protection: | Complete suit protecting against chemicals (EN 340) The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace and shoes that cover the entire foot. |
| 8.2.2.3. | Respiratory protection: | Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type P3 (EN 143) respirator cartridges as a backup to engineering controls. |
| 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: | colorless | No information available |
| | Odour/odour threshold: | sharp/no information available | No information available |
| | Melting point / freezing point: | No information available | No information available |
| | Boiling point or initial boiling point and boiling range: | No information available | No information available |
| | Flammability: | No information available | No information available |

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| | Lower and upper explosion limit: | No information available | No information available |
| | Flash point: | No information available | No information available |
| | Auto-ignition temperature: | No information available | No information available |
| | Decomposition temperature: | No information available | No information available |
| | pH: | 6.9-7.1 | No information available |
| | Kinematic viscosity: | No information available | No information available |
| | Solubility: | No information available | No information available |
| | Partition coefficient n-octanol/water (log value): | No information available | No information available |
| | Vapour pressure: | No information available | No information available |
| | Density and/or relative density | No information available | No information available |
| | Relative vapour density: | No information available | No information available |
| | Particle characteristics: | No information available | No information available |
| 9.2. | Other information | | |
| | - | | |

SECTION 10.: Stability and reactivity

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|-------|-------------------------------------|---|
| 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 information available |
| 10.4. | Conditions to avoid: | No information available |
| 10.5. | Incompatible materials: | Strong oxidizing agents. |
| 10.6. | Hazardous decomposition products: | Carbon oxides. |

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 (paraformaldehyde) | LD ₅₀ | No information available | 800 mg/kg |
| Dermal | No information available | rabbit (paraformaldehyde) | LD ₅₀ | No information available | 10.000 mg/kg |

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|------------|--------------------------|---------------------------|------------------|-----|-----------|
| Inhalation | No information available | rat (paraformaldehyde) | LC ₅₀ | 4 h | 1.07 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 | May cause respiratory irritation. - Respiratory system |

Aspiration hazard: no information available

Irritation and corrosion

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

Sensitization

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| Skin sensitization: | May cause an allergic skin reaction. |
| Respiratory sensitization: | Allergic persons may display irritation. |

Symptoms related to the physical, chemical and toxicological characteristics

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| Oral exposure: | Depending on concentration and exposure time, mucous membranes with retrosternal and abdominal pain, cramps, bloody vomiting, cyanosis, respiratory insufficiency, danger of perforation of the esophagus, stomach and small intestine; absorptive-toxic effects; delayed development of strictures possible. |
| Dermal exposure: | Depending on concentration and exposure time, superficial coagulation necrosis with hardening and tanning of the skin as well as anesthesia, allergic skin reactions (periorbital edema, urticaria, delayed development of eczema). |
| Inhalation exposure: | Depending on concentration and exposure time, irritation to the mucous membranes of the nose/throat (burning sensation, urge to sneeze, running nose), possibly even asthmoid reactions; for higher concentrations severe difficulty in breathing, fits of coughing, tightness in the chest, headache, reactions of the circulatory system, danger of glottic edema/cramp, bronchospasm, possible bronchiolitis, pneumonia, pulmonary edema |

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| Eye exposure: | Dependent on the intensity of exposure slight, reversible irritation through to permanent corneal lesion: seriousness probably only visible after a latency period of some hours. |
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Repeated dose toxicity (subacute, subchronic, chronic)

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

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

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

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

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| CMR effects (carcinogenicity, mutagenicity, reproductive toxicity) | |
| Carcinogenicity: | Presumed to have carcinogenic potential for humans |
| Mutagenicity <i>In-vitro</i> : | No information available |
| Genotoxicity: | No information available |
| Mutagenicity <i>In-vivo</i> : | No information available |
| Germ cell mutagenicity: | Suspected of causing genetic defects. |
| Reproductive toxicity: | No information available |

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| Summary of evaluation of the CMR properties: | No information available |
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11.2. Information on other hazards:

11.2.1. Endocrine disrupting properties:

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| The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |
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11.2.2. Other information:

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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 | <i>Oncorhynchus mykiss</i> (rainbow trout) | No information available | 46 – 78 mg/l (paraformaldehyde) | - |
| Crustacea: | EC ₅₀ | 48 hours | <i>Daphnia magna</i> (water flea) | No information available | 42 mg/l (paraformaldehyde) | - |

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| Algae/aquatic plants: | IC ₅₀ | 8 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: | - | - | - | - | - | - |

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

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| 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 (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 | - | |

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| 12.5. | Results of PBT and vPvB assessment |
| | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. |
| 12.6. | Endocrine disrupting properties |
| | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |
| 12.7. | 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: |
| | 15 01 10*: 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: |
| | - |

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|---------------|-------------------|----------------------|------------------|----------|---|
| Trade name: | IMMUNOFORM | | | | |
| Product code: | IMF-X** | Date of compilation: | 21 December 2022 | Version: | 3 |

| SECTION 14. Transport information | |
|---|--|
| Transporting/shipment by road (ADR) | |
| UN number | Not regulated |
| UN proper shipping name: | - |
| Transport hazard classes: | - |
| Packing group: | - |
| Environmental hazards: | - |
| Special precautions for user: | - |
| Transporting/shipment by rail (RID) | |
| UN number | Not regulated |
| UN proper shipping name: | - |
| Transport hazard classes: | - |
| Packing group: | - |
| Environmental hazards: | - |
| Special precautions for user: | - |
| Transporting/shipment by inland waterways (ADN) | |
| UN number | Not regulated |
| UN proper shipping name: | - |
| Transport hazard classes: | - |
| Packing group: | - |
| Environmental hazards: | - |
| Special precautions for user: | - |
| Transporting/shipment by sea (IMDG) | |
| UN number | Not regulated |
| UN proper shipping name: | - |
| Transport hazard classes: | - |
| Packing group: | - |
| Environmental hazards: | - |
| 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 | 3334 |
| UN Proper shipping name: | Aviation regulated liquid, n.o.s. (formaldehyde) |
| Transport hazard classes: | 9 |
| Packing group: | III |

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| Environmentally hazardous: | no |
| Special precautions for user: | - |
| Further information: | No information available |

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

SECTION 16. Other information

| | | |
|-------|------------------------|---|
| 16.1. | Indication of changes: | - |
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| Trade name: | IMMUNOFORM | | | | |
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| | | |
|-------|---|---|
| 16.2. | Abbreviations and acronyms: | <p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p> |
| 16.3. | Key literature references and source of data: | - |
| 16.4. | Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP) | |
| | Classification | Classification procedure |
| | - | - |
| 16.5. | Relevant H statements (number and full text) | |
| | 302 | Harmful if swallowed. |
| | 315 | Causes skin irritation. |
| H: | 317 | May cause allergic skin reaction. |
| | 318 | Causes serious eye damage. |
| | 332 | Harmful if inhaled. |
| | 335 | May cause respiratory irritation. |
| | 341 | Suspected of causing genetic defects. |
| | 350 | May cause cancer. |
| 16.6. | Training advice: | - |
| 16.7. | Further notice: | <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> |

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| ANNEX: Exposure scenario resulting to Chemical safety assessment |
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