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|---------------|----------------------------------|----------------------|--------------|------------|
| Trade name: | ORANGE II REAGENT, PAP 2B | | | |
| Product code: | OR2-OT-X** | Date of compilation: | 05 June 2019 | Version: 1 |

| SECTION 1: Identification of the substance/mixture and of the company/undertaking | | |
|--|---|---|
| 1.1. | Product identifier | |
| | Trade name: | ORANGE II REAGENT, PAP 2B |
| | Chemical name: | - |
| | Catalogue number: | OR2-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 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: | ORANGE II REAGENT, PAP 2B |
| | Identification number: | - |
| | Authorisation number: | - |

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| 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 | |

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

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| 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: | no information available | 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 |

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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 available information | rat | LD ₅₀ | - | 7.060 mg/kg (ethanol) 7.712 mg/kg (ethylene glycol) |
| Dermal: | No available information | rabbit | LD ₅₀ | - | >3.500mg/kg (ethylene glycol) |
| Inhalation: | No available information | 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 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

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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 |
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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: | - |
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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. | <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: | ORANGE II REAGENT, PAP 2B | | | | |
| Product code: | OR2-OT-X** | Date of compilation: | 05 June 2019 | Version: | 1 |

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