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

### 1.1. Product identifier

Product form : Mixture
Product name : **EmbryoFreeze - Freezing medium**
Product code : EMF01_P_F

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : Medium for freezing human embryos

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

FertiPro NV
Industriepark Noord 32
8730 Beernem
Belgium
info@fertipro.com

### 1.4. Emergency telephone number

Emergency number : +3250791805

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

**Adverse physicochemical, human health and environmental effects**

No additional information available

### 2.2. Label elements

**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

No labelling applicable

### 2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---|---|---|
| Ultrapure water | (CAS No) 7732-18-5<br>(EC No) 231-791-2 | 70 - 90 | Not classified |
| Propylene Glycol | (CAS No) 57-55-6<br>(EC No) 200-338-0 | 10 - 20 | Not classified |
| Sucrose | (CAS No) 57-50-1<br>(EC No) 200-334-9 | 1 - 5 | Not classified |
| Human Serum Albumin | (CAS No) 70024-90-7 | 1-5 | Not classified |
| Sodium Chloride | (CAS No) 7647-14-5<br>(EC No) 231-598-3 | 0,1 - 1 | Not classified |
| Disodium Phosphate Dihydrate | (CAS No) 10028-24-7 | 0,1 - 1 | Not classified |
| Potassium Chloride | (CAS No) 7447-40-7<br>(EC No) 231-211-8 | < 0,1 | Not classified |

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---|---|---|
| Potassiom Dihydrogen Phosphate | (CAS No) 7778-77-0<br>(EC No) 231-913-4 | < 0,1 | Not classified |

Comments : The media do not contain any raw materials of direct animal-origin or materials that have been produced using animal-origin components. Components have not been in contact with material of animal origin during processing and therefore pose no TSE risk

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Allow affected person to breathe fresh air. Allow the victim to rest.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

No additional information available

### 5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills as soon as possible. Collect spillage. Store away from other materials.

### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

### 7.2. Conditions for safe storage, including any incompatibilities

| | | |
|---|---|---|
| Storage conditions | : | Do not freeze. Do not use after expiry date. After opening the container, the product can be safely used up to 7 days when sterile conditions are maintained and the products are stored at 2-8°C. Cannot be re-sterilized after opening. Keep only in the original container in a cool, well ventilated place away from : direct (sun)light. Keep container closed when not in use. |
| Incompatible products | : | Strong bases. Strong acids. |
| Incompatible materials | : | Sources of ignition. Direct (sun)light. |
| Storage temperature | : | 2 - 8 °C |

### 7.3. Specific end use(s)

See instructions for use delivered with the device.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

#### 8.2.2. Personal protection equipment

**Personal protective equipment:**

Avoid all unnecessary exposure.

**Personal protective equipment symbol(s):**

#### 8.2.2.1. Eye and face protection

| **Eye/Face protection:** |
|---|
| Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU). |

#### 8.2.2.2. Skin protection

| **Hand protection:** |
|---|
| Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.<br>The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it. |

| **Skin protection:** |
|---|
| Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace. |

#### 8.2.2.3. Respiratory protection

| **Respiratory protection:** |
|---|
| Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). |

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

**Other information:**

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | Liquid |
| Colour | : | Clear colourless liquid. |
| Odour | : | Odourless. |
| Odour threshold | : | Not available |
| Melting point | : | Not available |
| Freezing point | : | Not available |
| Boiling point | : | Not available |
| Flammability | : | Non flammable |
| Explosive limits | : | Not available |
| Lower explosion limit | : | Not available |
| Upper explosion limit | : | Not available |
| Flash point | : | Not available |
| Auto-ignition temperature | : | Not available |
| Decomposition temperature | : | Not available |
| pH | : | pH: 7.2 – 7.4 |
| Viscosity, kinematic | : | Not available |
| Solubility | : | Highly soluble in water.<br>Water: complete |
| Partition coefficient n-octanol/water (Log Kow) | : | Not available |
| Vapour pressure | : | Not available |
| Vapour pressure at 50 °C | : | Not available |
| Density | : | Not available |
| Relative density | : | Not available |
| Relative vapour density at 20 °C | : | Not available |
| Particle characteristics | : | Not applicable |

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable after transport (max. 5 days) at elevated temperature (≤ 37°C). Stable for 18 months from date of manufacture.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. Fume.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

| | | |
|---|---|---|
| Acute toxicity (oral, dermal, inhalation) | : | Not classified<br>Extensive data on Mouse Embryo Assays have demonstrated that the medium is not toxic. |
| Skin corrosion/irritation | : | Not classified<br>pH: 7.2 – 7.4 |
| Additional information | : | Based on available data, the classification criteria are not met |
| Serious eye damage/irritation | : | Not classified<br>pH: 7.2 – 7.4 |
| Additional information | : | Based on available data, the classification criteria are not met |
| Respiratory or skin sensitisation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Germ cell mutagenicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Carcinogenicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Reproductive toxicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Specific target organ toxicity (single exposure) | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Specific target organ toxicity (repeated exposure) | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Aspiration hazard | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

No additional information available

#### 11.2.2. Other information

| | | |
|---|---|---|
| Potential adverse human health effects and symptoms | : | Based on available data, the classification criteria are not met |
| Other information | : | Human Serum Albumin: The plasma which is the source of the human serum albumin is tested for antibodies to HIV and HCV and non-reactive for HbsAg, HBV RNA, HCV RNA, HIV-1 RNA and syphilis. The albumin agrees with all the requirements set forth by the European and United States health authority regarding safety. Routes of exposure: Under normal conditions, there is no exposure of the patient to the medium. |

## SECTION 12: Ecological information

### 12.1. Toxicity

| | | |
|---|---|---|
| Hazardous to the aquatic environment, short-term (acute) | : | Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : | Not classified |

### 12.2. Persistence and degradability

| **EmbryoFreeze - Freezing medium** | |
|---|---|
| Persistence and degradability | Not established. |

| **Sodium Chloride (7647-14-5)** | |
|---|---|
| Persistence and degradability | Not established. |

### 12.3. Bioaccumulative potential

| **EmbryoFreeze - Freezing medium** | |
|---|---|
| Bioaccumulative potential | Not established. |

| **Sodium Chloride (7647-14-5)** | |
|---|---|
| Bioaccumulative potential | Not established. |

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

### 14.1. UN number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

UN-No. (ADN) : Not applicable

UN-No. (RID) : Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

Proper Shipping Name (ADN) : Not applicable

Proper Shipping Name (RID) : Not applicable

### 14.3. Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable

Transport hazard class(es) (IMDG) : Not applicable

Transport hazard class(es) (IATA) : Not applicable

Transport hazard class(es) (ADN) : Not applicable

Transport hazard class(es) (RID) : Not applicable

### 14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

### 14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

### 14.6. Special precautions for user

**Overland transport**

No data available

**Transport by sea**

No data available

**Air transport**

No data available

**Inland waterway transport**

No data available

**Rail transport**

No data available

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.
Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.
Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

#### 15.1.2. National regulations

**France**

**Occupational diseases**

| Code | Description |
|---|---|
| RG 67 | Nasal septum lesions caused by potassium chloride dust in potash mines and their dependencies |
| RG 78 | Diseases caused by sodium chloride in salt mines and their dependencies |
| RG 84 | Conditions caused by liquid organic solvents for professional use: saturated or unsaturated aliphatic or cyclic liquid hydrocarbons and mixtures thereof; liquid halogenated hydrocarbons; nitrated derivatives of aliphatic hydrocarbons; alcohols; glycols, glycol ethers; ketones; aldehydes; aliphatic and cyclic ethers, including tetrahydrofuran; esters; dimethylformamide and dimethylacetamine; acetonitrile and propionitrile; pyridine; dimethylsulfone and dimethylsulfoxide |

**Germany**

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1)
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

**Netherlands**

SZW-list of carcinogenic substances : None of the components are listed
SZW-list of mutagenic substances : None of the components are listed
NON-exhaustive list of reproductive toxins - Breastfeeding : None of the components are listed
NON-exhaustive list of reproductive toxins - Fertility : None of the components are listed
NON-exhaustive list of reproductive toxins – Development : None of the components are listed

**Switzerland**

Storage class (LK) : LK 10/12 - Liquids

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Data sources : 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.

Other information : None.

SDS EU (REACH Annex II)
*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*

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

### 1.1. Product identifier

Product form : Mixture

Product name : **EmbryoThaw- Thaw 1**

Product code : EMF01_P_T1

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only

Use of the substance/mixture : Medium for thawing human embryos

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

FertiPro NV
Industriepark Noord 32
8730 Beernem
Belgium
info@fertipro.com

### 1.4. Emergency telephone number

Emergency number : +3250791805

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

**Adverse physicochemical, human health and environmental effects**

No additional information available

### 2.2. Label elements

**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

No labelling applicable

### 2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---|---|---|
| Ultrapure water | (CAS No) 7732-18-5<br>(EC No) 231-791-2 | 70 - 90 | Not classified |
| Sucrose | (CAS No) 57-50-1<br>(EC No) 200-334-9 | 5 - 10 | Not classified |
| Propylene Glycol | (CAS No) 57-55-6<br>(EC No) 200-338-0 | 5 - 10 | Not classified |
| Human Serum Albumin | (CAS No) 70024-90-7 | 1 - 5 | Not classified |
| Sodium Chloride | (CAS No) 7647-14-5<br>(EC No) 231-598-3 | 0,1 - 1 | Not classified |
| Disodium Phosphate Dihydrate | (CAS No) 10028-24-7 | 0,1 - 1 | Not classified |
| Potassium Chloride | (CAS No) 7447-40-7<br>(EC No) 231-211-8 | < 0,1 | Not classified |
| Potassiom Dihydrogen Phosphate | (CAS No) 7778-77-0<br>(EC No) 231-913-4 | < 0,1 | Not classified |

| | | |
|---|---|---|
| Comments | : | The media do not contain any raw materials of direct animal-origin or materials that have been produced using animal-origin components. Components have not been in contact with material of animal origin during processing and therefore pose no TSE risk |

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

| | | |
|---|---|---|
| First-aid measures general | : | Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). |
| First-aid measures after inhalation | : | Allow affected person to breathe fresh air. Allow the victim to rest. |
| First-aid measures after skin contact | : | Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. |
| First-aid measures after eye contact | : | Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist. |
| First-aid measures after ingestion | : | Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. |

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

| | | |
|---|---|---|
| Symptoms/injuries | : | Not expected to present a significant hazard under anticipated conditions of normal use. |

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

| | | |
|---|---|---|
| Suitable extinguishing media | : | Foam. Dry powder. Carbon dioxide. Water spray. Sand. |
| Unsuitable extinguishing media | : | Do not use a heavy water stream. |

### 5.2. Special hazards arising from the substance or mixture

No additional information available

### 5.3. Advice for firefighters

| | | |
|---|---|---|
| Firefighting instructions | : | Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment. |
| Protection during firefighting | : | Do not enter fire area without proper protective equipment, including respiratory protection. |

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

| | | |
|---|---|---|
| Emergency procedures | : | Evacuate unnecessary personnel. |

#### 6.1.2. For emergency responders

| | | |
|---|---|---|
| Protective equipment | : | Equip cleanup crew with proper protection. |
| Emergency procedures | : | Ventilate area. |

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

| | | |
|---|---|---|
| Methods for cleaning up | : | Soak up spills as soon as possible. Collect spillage. Store away from other materials. |

### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

| | | |
|---|---|---|
| Precautions for safe handling | : | Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. |

### 7.2. Conditions for safe storage, including any incompatibilities

| | | |
|---|---|---|
| Storage conditions | : | Do not use after expiry date. After opening the container, the product can be safely used up to 7 days when sterile conditions are maintained and the products are stored at 2-8°C. Cannot be re-sterilized after opening. Keep only in the original container in a cool, well ventilated place away from direct (sun)light. Keep container closed when not in use. |
| Incompatible products | : | Strong bases. Strong acids. |
| Incompatible materials | : | Sources of ignition. Direct (sun)light. |

Storage temperature : 2 - 8 °C

### 7.3. Specific end use(s)

See instructions for use delivered with the device.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

#### 8.2.2. Personal protection equipment

**Personal protective equipment:**

Avoid all unnecessary exposure.

**Personal protective equipment symbol(s):**

#### 8.2.2.1. Eye and face protection

| **Eye/Face protection:** |
|---|
| Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU). |

#### 8.2.2.2. Skin protection

| **Hand protection:** |
|---|
| Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.<br>The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it. |

| **Skin protection:** |
|---|
| Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace. |

#### 8.2.2.3. Respiratory protection

| **Respiratory protection:** |
|---|
| Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). |

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

**Other information:**

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | Liquid |
| Colour | : | Clear colorless liquid. |
| Odour | : | Odourless. |
| Odour threshold | : | Not available |
| Melting point | : | Not available |
| Freezing point | : | Not available |
| Boiling point | : | Not available |
| Flammability | : | Non flammable |
| Explosive limits | : | Not available |
| Lower explosion limit | : | Not available |
| Upper explosion limit | : | Not available |
| Flash point | : | Not available |
| Auto-ignition temperature | : | Not available |
| Decomposition temperature | : | Not available |
| pH | : | 7,20 - 7,40 |
| Viscosity, kinematic | : | Not available |
| Solubility | : | Highly soluble in water.<br>Water: complete |
| Partition coefficient n-octanol/water (Log Kow) | : | Not available |
| Vapour pressure | : | Not available |
| Vapour pressure at 50 °C | : | Not available |
| Density | : | Not available |
| Relative density | : | Not available |
| Relative vapour density at 20 °C | : | Not available |
| Particle characteristics | : | Not applicable |

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable after transport (max. 5 days) at elevated temperature (≤ 37°C). Stable for 18 months from date of manufacture.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. Fume.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

| | | |
|---|---|---|
| Acute toxicity (oral, dermal, inhalation) | : | Not classified<br>Extensive data on Mouse Embryo Assays have demonstrated that the medium is not toxic. |
| Skin corrosion/irritation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Serious eye damage/irritation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Respiratory or skin sensitisation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Germ cell mutagenicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Carcinogenicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Reproductive toxicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Specific target organ toxicity (single exposure) | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Specific target organ toxicity (repeated exposure) | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Aspiration hazard | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

No additional information available

#### 11.2.2. Other information

| | | |
|---|---|---|
| Potential adverse human health effects and symptoms | : | Based on available data, the classification criteria are not met |
| Other information | : | Human Serum Albumin: The plasma which is the source of the human serum albumin is tested for antibodies to HIV and HCV and non-reactive for HbsAg, HBV RNA, HCV RNA, HIV-1 RNA and syphilis. The albumin agrees with all the requirements set forth by the European and United States health authority regarding safety. Routes of exposure: Under normal conditions, there is no exposure of the patient to the medium. |

## SECTION 12: Ecological information

### 12.1. Toxicity

| | | |
|---|---|---|
| Hazardous to the aquatic environment, short-term (acute) | : | Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : | Not classified |

### 12.2. Persistence and degradability

| **EmbryoThaw- Thaw 1** | |
|---|---|
| Persistence and degradability | Not established. |

| **Sodium Chloride (7647-14-5)** | |
|---|---|
| Persistence and degradability | Not established. |

### 12.3. Bioaccumulative potential

| **EmbryoThaw- Thaw 1** | |
|---|---|
| Bioaccumulative potential | Not established. |

| **Sodium Chloride (7647-14-5)** | |
|---|---|
| Bioaccumulative potential | Not established. |

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

### 14.1. UN number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

UN-No. (ADN) : Not applicable

UN-No. (RID) : Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

Proper Shipping Name (ADN) : Not applicable

Proper Shipping Name (RID) : Not applicable

### 14.3. Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable

Transport hazard class(es) (IMDG) : Not applicable

Transport hazard class(es) (IATA) : Not applicable

Transport hazard class(es) (ADN) : Not applicable

Transport hazard class(es) (RID) : Not applicable

### 14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

### 14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

### 14.6. Special precautions for user

**Overland transport**

No data available

**Transport by sea**

No data available

**Air transport**

No data available

**Inland waterway transport**

No data available

**Rail transport**

No data available

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.
Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.
Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

#### 15.1.2. National regulations

| **France** | |
|---|---|
| **Occupational diseases** | |
| **Code** | **Description** |
| RG 67 | Nasal septum lesions caused by potassium chloride dust in potash mines and their dependencies |
| RG 78 | Diseases caused by sodium chloride in salt mines and their dependencies |
| RG 84 | Conditions caused by liquid organic solvents for professional use: saturated or unsaturated aliphatic or cyclic liquid hydrocarbons and mixtures thereof; liquid halogenated hydrocarbons; nitrated derivatives of aliphatic hydrocarbons; alcohols; glycols, glycol ethers; ketones; aldehydes; aliphatic and cyclic ethers, including tetrahydrofuran; esters; dimethylformamide and dimethylacetamine; acetonitrile and propionitrile; pyridine; dimethylsulfone and dimethylsulfoxide |

**Germany**

| | | |
|---|---|---|
| Water hazard class (WGK) | : | WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1) |
| Hazardous Incident Ordinance (12. BImSchV) | : | Is not subject of the Hazardous Incident Ordinance (12. BImSchV) |

**Netherlands**

| | | |
|---|---|---|
| SZW-list of carcinogenic substances | : | None of the components are listed |
| SZW-list of mutagenic substances | : | None of the components are listed |
| NON-exhaustive list of reproductive toxins - Breastfeeding | : | None of the components are listed |
| NON-exhaustive list of reproductive toxins - Fertility | : | None of the components are listed |
| NON-exhaustive list of reproductive toxins – Development | : | None of the components are listed |

**Switzerland**

| | | |
|---|---|---|
| Storage class (LK) | : | LK 10/12 - Liquids |

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

| | | |
|---|---|---|
| Data sources | : | 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. |
| Other information | : | None. |

SDS EU (REACH Annex II)
*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*

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

### 1.1. Product identifier

Product form : Mixture

Product name : **EmbryoThaw - Thaw 2**

Product code : EMF01_P_T2

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only

Use of the substance/mixture : Medium for thawing human embryos

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

FertiPro NV
Industriepark Noord 32
8730 Beernem
Belgium
info@fertipro.com

### 1.4. Emergency telephone number

Emergency number : +3250791805

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

**Adverse physicochemical, human health and environmental effects**

No additional information available

### 2.2. Label elements

**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

No labelling applicable

### 2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---|---|---|
| Ultrapure water | (CAS No) 7732-18-5<br>(EC No) 231-791-2 | 70 - 90 | Not classified |
| Sucrose | (CAS No) 57-50-1<br>(EC No) 200-334-9 | 5 - 10 | Not classified |
| Propylene Glycol | (CAS No) 57-55-6<br>(EC No) 200-338-0 | 1 - 5 | Not classified |
| Human serum albumin | (CAS No) 70024-90-7 | 1 - 5 | Not classified |
| Sodium Chloride | (CAS No) 7647-14-5<br>(EC No) 231-598-3 | 0,1 - 1 | Not classified |
| Disodium Phosphate Dihydrate | (CAS No) 10028-24-7 | 0,1 - 1 | Not classified |
| Potassium Chloride | (CAS No) 7447-40-7<br>(EC No) 231-211-8 | < 0,1 | Not classified |
| Potassium Dihydrogen Phosphate | (CAS No) 7778-77-0<br>(EC No) 231-913-4 | < 0,1 | Not classified |

| | | |
|---|---|---|
| Comments | : | The media do not contain any raw materials of direct animal-origin or materials that have been produced using animal-origin components. Components have not been in contact with material of animal origin during processing and therefore pose no TSE risk |

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

| | | |
|---|---|---|
| First-aid measures general | : | Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). |
| First-aid measures after inhalation | : | Allow affected person to breathe fresh air. Allow the victim to rest. |
| First-aid measures after skin contact | : | Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. |
| First-aid measures after eye contact | : | Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist. |
| First-aid measures after ingestion | : | Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. |

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

| | | |
|---|---|---|
| Symptoms/injuries | : | Not expected to present a significant hazard under anticipated conditions of normal use. |

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

| | | |
|---|---|---|
| Suitable extinguishing media | : | Foam. Dry powder. Carbon dioxide. Water spray. Sand. |
| Unsuitable extinguishing media | : | Do not use a heavy water stream. |

### 5.2. Special hazards arising from the substance or mixture

No additional information available

### 5.3. Advice for firefighters

| | | |
|---|---|---|
| Firefighting instructions | : | Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment. |
| Protection during firefighting | : | Do not enter fire area without proper protective equipment, including respiratory protection. |

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

| | | |
|---|---|---|
| Emergency procedures | : | Evacuate unnecessary personnel. |

#### 6.1.2. For emergency responders

| | | |
|---|---|---|
| Protective equipment | : | Equip cleanup crew with proper protection. |
| Emergency procedures | : | Ventilate area. |

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

| | | |
|---|---|---|
| Methods for cleaning up | : | Soak up spills as soon as possible. Collect spillage. Store away from other materials. |

### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

| | | |
|---|---|---|
| Precautions for safe handling | : | Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. |

### 7.2. Conditions for safe storage, including any incompatibilities

| | | |
|---|---|---|
| Storage conditions | : | Do not use after expiry date. After opening the container, the product can be safely used up to 7 days when sterile conditions are maintained and the products are stored at 2-8°C. Cannot be re-sterilized after opening. Keep only in the original container in a cool, well ventilated place away from direct (sun)light. Keep container closed when not in use. |
| Incompatible products | : | Strong bases. Strong acids. |

| | | |
|---|---|---|
| Incompatible materials | : | Sources of ignition. Direct (sun)light. |
| Storage temperature | : | 2 - 8 °C |

### 7.3. Specific end use(s)

See intstructions for use delivered with the device.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

#### 8.2.2. Personal protection equipment

**Personal protective equipment:**

Avoid all unnecessary exposure.

**Personal protective equipment symbol(s):**

#### 8.2.2.1. Eye and face protection

| **Eye/Face protection:** |
|---|
| Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU). |

#### 8.2.2.2. Skin protection

| **Hand protection:** |
|---|
| Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.<br>The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it. |

| **Skin protection:** |
|---|
| Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace. |

#### 8.2.2.3. Respiratory protection

| **Respiratory protection:** |
|---|
| Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). |

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

**Other information:**

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | Liquid |
| Colour | : | Clear, colorless liquid. |
| Appearance | : | Colourless. |
| Odour | : | Odourless. |
| Odour threshold | : | Not available |
| Melting point | : | Not available |
| Freezing point | : | Not available |
| Boiling point | : | Not available |
| Flammability | : | Non flammable |
| Explosive limits | : | Not available |
| Lower explosion limit | : | Not available |
| Upper explosion limit | : | Not available |
| Flash point | : | Not available |
| Auto-ignition temperature | : | Not available |
| Decomposition temperature | : | Not available |
| pH | : | 7,20 - 7,40 |
| Viscosity, kinematic | : | Not available |
| Solubility | : | Highly soluble in water.<br>Water: complete |
| Partition coefficient n-octanol/water (Log Kow) | : | Not available |
| Vapour pressure | : | Not available |
| Vapour pressure at 50 °C | : | Not available |
| Density | : | Not available |
| Relative density | : | Not available |
| Relative vapour density at 20 °C | : | Not available |
| Particle characteristics | : | Not applicable |

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable after transport (max. 5 days) at elevated temperature (≤ 37°C). Stable for 18 months from date of manufacture.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. Fume.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

| | | |
|---|---|---|
| Acute toxicity (oral, dermal, inhalation) | : | Not classified<br>Extensive data on Mouse Embryo Assays have demonstrated that the medium is not toxic. |
| Skin corrosion/irritation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Serious eye damage/irritation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Respiratory or skin sensitisation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Germ cell mutagenicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Carcinogenicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Reproductive toxicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Specific target organ toxicity (single exposure) | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Specific target organ toxicity (repeated exposure) | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Aspiration hazard | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

No additional information available

#### 11.2.2. Other information

| | | |
|---|---|---|
| Potential adverse human health effects and symptoms | : | Based on available data, the classification criteria are not met |
| Other information | : | Human Serum Albumin: The plasma which is the source of the human serum albumin is tested for antibodies to HIV and HCV and non-reactive for HbsAg, HBV RNA, HCV RNA, HIV-1 RNA and syphilis. The albumin agrees with all the requirements set forth by the European and United States health authority regarding safety.<br>Routes of exposure: Under normal conditions, there is no exposure of the patient to the medium. |

## SECTION 12: Ecological information

### 12.1. Toxicity

| | | |
|---|---|---|
| Hazardous to the aquatic environment, short-term (acute) | : | Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : | Not classified |

### 12.2. Persistence and degradability

| **EmbryoThaw - Thaw 2** | |
|---|---|
| Persistence and degradability | Not established. |

| **Sodium Chloride (7647-14-5)** | |
|---|---|
| Persistence and degradability | Not established. |

### 12.3. Bioaccumulative potential

| **EmbryoThaw - Thaw 2** | |
|---|---|
| Bioaccumulative potential | Not established. |

| **Sodium Chloride (7647-14-5)** | |
|---|---|
| Bioaccumulative potential | Not established. |

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

### 14.1. UN number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

UN-No. (ADN) : Not applicable

UN-No. (RID) : Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

Proper Shipping Name (ADN) : Not applicable

Proper Shipping Name (RID) : Not applicable

### 14.3. Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable

Transport hazard class(es) (IMDG) : Not applicable

Transport hazard class(es) (IATA) : Not applicable

Transport hazard class(es) (ADN) : Not applicable

Transport hazard class(es) (RID) : Not applicable

### 14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

### 14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

### 14.6. Special precautions for user

**Overland transport**

No data available

**Transport by sea**

No data available

**Air transport**

No data available

**Inland waterway transport**

No data available

**Rail transport**

No data available

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.
Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.
Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

#### 15.1.2. National regulations

| **France** | |
|---|---|
| **Occupational diseases** | |
| **Code** | **Description** |
| RG 67 | Nasal septum lesions caused by potassium chloride dust in potash mines and their dependencies |
| RG 78 | Diseases caused by sodium chloride in salt mines and their dependencies |
| RG 84 | Conditions caused by liquid organic solvents for professional use: saturated or unsaturated aliphatic or cyclic liquid hydrocarbons and mixtures thereof; liquid halogenated hydrocarbons; nitrated derivatives of aliphatic hydrocarbons; alcohols; glycols, glycol ethers; ketones; aldehydes; aliphatic and cyclic ethers, including tetrahydrofuran; esters; dimethylformamide and dimethylacetamine; acetonitrile and propionitrile; pyridine; dimethylsulfone and dimethylsulfoxide |

**Germany**

| | | |
|---|---|---|
| Water hazard class (WGK) | : | WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1) |
| Hazardous Incident Ordinance (12. BImSchV) | : | Is not subject of the Hazardous Incident Ordinance (12. BImSchV) |

**Netherlands**

| | | |
|---|---|---|
| SZW-list of carcinogenic substances | : | None of the components are listed |
| SZW-list of mutagenic substances | : | None of the components are listed |
| NON-exhaustive list of reproductive toxins - Breastfeeding | : | None of the components are listed |
| NON-exhaustive list of reproductive toxins - Fertility | : | None of the components are listed |
| NON-exhaustive list of reproductive toxins – Development | : | None of the components are listed |

**Switzerland**

| | | |
|---|---|---|
| Storage class (LK) | : | LK 10/12 - Liquids |

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

| | | |
|---|---|---|
| Data sources | : | 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. |
| Other information | : | None. |

SDS EU (REACH Annex II)
*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*

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

### 1.1. Product identifier

Product form : Mixture

Product name : **EmbryoThaw - Thaw 3**

Product code : EMF01_P_T3

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only

Use of the substance/mixture : Medium for thawing human embryos

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

FertiPro NV
Industriepark Noord 32
8730 Beernem
Belgium
info@fertipro.com

### 1.4. Emergency telephone number

Emergency number : +3250791805

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

**Adverse physicochemical, human health and environmental effects**

No additional information available

### 2.2. Label elements

**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

No labelling applicable

### 2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---|---|---|
| Ultrapure water | (CAS No) 7732-18-5<br>(EC No) 231-791-2 | 70 - 90 | Not classified |
| Sucrose | (CAS No) 57-50-1<br>(EC No) 200-334-9 | 5 - 10 | Not classified |
| Human serum albumin | (CAS No) 70024-90-7 | 1 - 5 | Not classified |
| Sodium Chloride | (CAS No) 7647-14-5<br>(EC No) 231-598-3 | 0,1 - 1 | Not classified |
| Potassium Chloride | (CAS No) 7447-40-7<br>(EC No) 231-211-8 | 0,1 - 1 | Not classified |
| Disodium Phosphate Dihydrate | (CAS No) 10028-24-7 | 0,1 - 1 | Not classified |
| Potassiom Dihydrogen Phosphate | (CAS No) 7778-77-0<br>(EC No) 231-913-4 | 0,1 - 1 | Not classified |

| | | |
|---|---|---|
| Comments | : | The media do not contain any raw materials of direct animal-origin or materials that have been produced using animal-origin components. Components have not been in contact with material of animal origin during processing and therefore pose no TSE risk |

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

| | | |
|---|---|---|
| First-aid measures general | : | Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). |
| First-aid measures after inhalation | : | Allow affected person to breathe fresh air. Allow the victim to rest. |
| First-aid measures after skin contact | : | Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. |
| First-aid measures after eye contact | : | Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist. |
| First-aid measures after ingestion | : | Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. |

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

| | | |
|---|---|---|
| Symptoms/injuries | : | Not expected to present a significant hazard under anticipated conditions of normal use. |

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

| | | |
|---|---|---|
| Suitable extinguishing media | : | Foam. Dry powder. Carbon dioxide. Water spray. Sand. |
| Unsuitable extinguishing media | : | Do not use a heavy water stream. |

### 5.2. Special hazards arising from the substance or mixture

No additional information available

### 5.3. Advice for firefighters

| | | |
|---|---|---|
| Firefighting instructions | : | Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment. |
| Protection during firefighting | : | Do not enter fire area without proper protective equipment, including respiratory protection. |

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

| | | |
|---|---|---|
| Emergency procedures | : | Evacuate unnecessary personnel. |

#### 6.1.2. For emergency responders

| | | |
|---|---|---|
| Protective equipment | : | Equip cleanup crew with proper protection. |
| Emergency procedures | : | Ventilate area. |

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

| | | |
|---|---|---|
| Methods for cleaning up | : | Soak up spills as soon as possible. Collect spillage. Store away from other materials. |

### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

| | | |
|---|---|---|
| Precautions for safe handling | : | Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. |

### 7.2. Conditions for safe storage, including any incompatibilities

| | | |
|---|---|---|
| Storage conditions | : | Do not use after expiry date. After opening the container, the product can be safely used up to 7 days when sterile conditions are maintained and the products are stored at 2-8°C. Cannot be re-sterilized after opening. Keep only in the original container in a cool, well ventilated place away from direct (sun)light. Keep container closed when not in use. |
| Incompatible products | : | Strong bases. Strong acids. |

| | |
|---|---|
| Incompatible materials | : Sources of ignition. Direct (sun)light. |
| Storage temperature | : 2 - 8 °C |

### 7.3. Specific end use(s)

See instructions for use delivered with the device.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

#### 8.2.2. Personal protection equipment

**Personal protective equipment:**

Avoid all unnecessary exposure.

**Personal protective equipment symbol(s):**

#### 8.2.2.1. Eye and face protection

| **Eye/Face protection:** |
|---|
| Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU). |

#### 8.2.2.2. Skin protection

| **Hand protection:** |
|---|
| Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.<br>The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it. |

| **Skin protection:** |
|---|
| Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace. |

#### 8.2.2.3. Respiratory protection

| **Respiratory protection:** |
|---|
| Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). |

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

**Other information:**

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | Liquid |
| Colour | : | Clear colorless liquid. |
| Odour | : | odourless. |
| Odour threshold | : | Not available |
| Melting point | : | Not available |
| Freezing point | : | Not available |
| Boiling point | : | Not available |
| Flammability | : | Non flammable |
| Explosive limits | : | Not available |
| Lower explosion limit | : | Not available |
| Upper explosion limit | : | Not available |
| Flash point | : | Not available |
| Auto-ignition temperature | : | Not available |
| Decomposition temperature | : | Not available |
| pH | : | 7,20 – 7,40 |
| Viscosity, kinematic | : | Not available |
| Solubility | : | Highly soluble in water.<br>Water: complete |
| Partition coefficient n-octanol/water (Log Kow) | : | Not available |
| Vapour pressure | : | Not available |
| Vapour pressure at 50 °C | : | Not available |
| Density | : | Not available |
| Relative density | : | Not available |
| Relative vapour density at 20 °C | : | Not available |
| Particle characteristics | : | Not applicable |

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable after transport (max. 5 days) at elevated temperature (≤ 37°C). Stable for 18 months from date of manufacture.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. Fume.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

| | | |
|---|---|---|
| Acute toxicity (oral, dermal, inhalation) | : | Not classified<br>Extensive data on Mouse Embryo Assays have demonstrated that the medium is not toxic. |
| Skin corrosion/irritation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Serious eye damage/irritation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Respiratory or skin sensitisation | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Germ cell mutagenicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Carcinogenicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Reproductive toxicity | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Specific target organ toxicity (single exposure) | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Specific target organ toxicity (repeated exposure) | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |
| Aspiration hazard | : | Not classified |
| Additional information | : | Based on available data, the classification criteria are not met |

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

No additional information available

#### 11.2.2. Other information

| | | |
|---|---|---|
| Potential adverse human health effects and symptoms | : | Based on available data, the classification criteria are not met |
| Other information | : | Human Serum Albumin: The plasma which is the source of the human serum albumin is tested for antibodies to HIV and HCV and non-reactive for HbsAg, HBV RNA, HCV RNA, HIV-1 RNA and syphilis. The albumin agrees with all the requirements set forth by the European and United States health authority regarding safety. Routes of exposure: Under normal conditions, there is no exposure of the patient to the medium. |

## SECTION 12: Ecological information

### 12.1. Toxicity

| | | |
|---|---|---|
| Hazardous to the aquatic environment, short-term (acute) | : | Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : | Not classified |

### 12.2. Persistence and degradability

| **EmbryoThaw - Thaw 3** | |
|---|---|
| Persistence and degradability | Not established. |

| **Sodium Chloride (7647-14-5)** | |
|---|---|
| Persistence and degradability | Not established. |

### 12.3. Bioaccumulative potential

| **EmbryoThaw - Thaw 3** | |
|---|---|
| Bioaccumulative potential | Not established. |

| **Sodium Chloride (7647-14-5)** | |
|---|---|
| Bioaccumulative potential | Not established. |

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

### 14.1. UN number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

### 14.3. Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable
Transport hazard class(es) (IMDG) : Not applicable
Transport hazard class(es) (IATA) : Not applicable
Transport hazard class(es) (ADN) : Not applicable
Transport hazard class(es) (RID) : Not applicable

### 14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

### 14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

### 14.6. Special precautions for user

**Overland transport**
No data available

**Transport by sea**
No data available

**Air transport**
No data available

**Inland waterway transport**
No data available

**Rail transport**
No data available

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.
Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.
Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

#### 15.1.2. National regulations

| **France** | |
|---|---|
| **Occupational diseases** | |
| **Code** | **Description** |
| RG 67 | Nasal septum lesions caused by potassium chloride dust in potash mines and their dependencies |
| RG 78 | Diseases caused by sodium chloride in salt mines and their dependencies |
| RG 84 | Conditions caused by liquid organic solvents for professional use: saturated or unsaturated aliphatic or cyclic liquid hydrocarbons and mixtures thereof; liquid halogenated hydrocarbons; nitrated derivatives of aliphatic hydrocarbons; alcohols; glycols, glycol ethers; ketones; aldehydes; aliphatic and cyclic ethers, including tetrahydrofuran; esters; dimethylformamide and dimethylacetamine; acetonitrile and propionitrile; pyridine; dimethylsulfone and dimethylsulfoxide |

**Germany**

| | | |
|---|---|---|
| Water hazard class (WGK) | : | WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1) |
| Hazardous Incident Ordinance (12. BImSchV) | : | Is not subject of the Hazardous Incident Ordinance (12. BImSchV) |

**Netherlands**

| | | |
|---|---|---|
| SZW-list of carcinogenic substances | : | None of the components are listed |
| SZW-list of mutagenic substances | : | None of the components are listed |
| NON-exhaustive list of reproductive toxins - Breastfeeding | : | None of the components are listed |
| NON-exhaustive list of reproductive toxins - Fertility | : | None of the components are listed |
| NON-exhaustive list of reproductive toxins – Development | : | None of the components are listed |

**Switzerland**

| | | |
|---|---|---|
| Storage class (LK) | : | LK 10/12 - Liquids |

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

| | | |
|---|---|---|
| Data sources | : | 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. |
| Other information | : | None. |

SDS EU (REACH Annex II)
*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*