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

1.1. Product identifier

Product form : Mixture

Product name : **VitriFreeze - Pre-incubation medium**

Product code : VPI005

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 : Cell culture medium for the vitrification of human embryos.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro N.V.
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

No additional information available

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 (EC no) 231-791-2	90 - 99	Not classified
Human Serum Albumin	(CAS No) 70024-90-7	1 - 5	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (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 (EC no) 231-211-8	< 0,1	Not classified
Potassium Dihydrogen Phosphate	(CAS No) 7778-77-0 (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 : Assure fresh air breathing. 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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : 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 : Keep container closed when not in use. Keep only in the original container away from direct (sun)light. 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-sterlized after opening.

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

No additional information available

8.2. Exposure controls

Appropriate engineering controls	:	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
Personal protective equipment	:	Wear fire/flame resistant/retardant clothing.
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.
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. The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it.
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).
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).
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	:	No data available
pH	:	7,2 - 7,4
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Non flammable
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	highly soluble in water. Water: complete
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

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 12 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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified. Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified
Potential adverse human health effects and symptoms	:	Based on available data, the classification criteria are not met.
Other information	:	Human Albumin Solution: 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. Route of exposure: Under normal conditions there is no exposure to the product.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

VitriFreeze - Pre-incubation medium	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

VitriFreeze - Pre-incubation medium	
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. 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

Not regulated for transport

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

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

Contains no REACH candidate substance

15.1.2. National regulations

No additional information available

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 : **VitriFreeze - Freezing 1**

Product code : VF1001

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 : Cell culture medium for the vitrification of human embryos.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro N.V.
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]

EUH phrases : EUH210 - Safety data sheet available on request

2.3. Other hazards

No additional information available

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 (EC no) 231-791-2	70 - 90	Not classified
Dimethyl sulphoxide (DMSO)	(CAS No) 67-68-5	10	Not classified
Ethylene glycol	(CAS No) 107-21-1 (EC no) 203-473-3 (EC index no) 603-027-00-1	10	Acute Tox. 4 (Oral), H302
Human serum albumin	(CAS No) 70024-90-7	1 - 5	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC no) 231-598-3	0,1 - 1	Not classified
Disodium Phosphate Dihydrate	(CAS No) 10028-24-7	< 0,1	Not classified
Potassium Chloride	(CAS No) 7447-40-7 (EC no) 231-211-8	< 0,1	Not classified
Potassium Dihydrogen Phosphate	(CAS No) 7778-77-0 (EC no) 231-913-4	< 0,1	Not classified

Full text of H-phrases: see section 16

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 : Assure fresh air breathing. 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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : 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 : Keep container closed when not in use.
Keep only in the original container away from direct (sun)light.
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-sterlized after opening.

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

No additional information available

8.2. Exposure controls

Appropriate engineering controls	:	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
Personal protective equipment	:	Wear fire/flame resistant/retardant clothing.
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.
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. The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it.
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).
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).
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	:	No data available
pH	:	7,2 - 7,4
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Non flammable
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	highly soluble in water. Water: complete
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

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 12 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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified. Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified
Potential adverse human health effects and symptoms	:	Based on available data, the classification criteria are not met.
Other information	:	Human Albumin Solution: 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. Route of exposure: Under normal conditions there is no exposure to the product.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

VitriFreeze – Freezing 1	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

VitriFreeze – Freezing 1	
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. 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

Not regulated for transport

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

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

Contains no REACH candidate substance

15.1.2. National regulations

No additional information available

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.

Full text of H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed

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 : **VitriFreeze - Freezing 2**
Product code : VF2001

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 : Cell culture medium for the vitrification of human embryos.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro N.V.
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]

EUH phrases : EUH210 - Safety data sheet available on request

2.3. Other hazards

No additional information available

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 (EC no) 231-791-2	50 - 70	Not classified
Sucrose	(CAS No) 57-50-1 (EC no) 200-334-9	20 - 30	Not classified
Dimethyl sulphoxide (DMSO)	(CAS No) 67-68-5	15 - 20	Not classified
Ethylene glycol	(CAS No) 107-21-1 (EC no) 203-473-3 (EC index no) 603-027-00-1	15 - 20	Acute Tox. 4 (Oral), H302
Human serum albumin	(CAS No) 70024-90-7	1 - 5	Not classified
Ficoll	(CAS No) 26873-85-8	0,1 - 1	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC no) 231-598-3	0,1 - 1	Not classified
Disodium Phosphate Dihydrate	(CAS No) 10028-24-7	< 0,1	Not classified
Potassium Chloride	(CAS No) 7447-40-7 (EC no) 231-211-8	< 0,1	Not classified
Potassium Dihydrogen Phosphate	(CAS No) 7778-77-0 (EC no) 231-913-4	< 0,1	Not classified

Full text of H-phrases: see section 16

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 : Assure fresh air breathing. 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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : 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 : Keep container closed when not in use.
Keep only in the original container away from direct (sun)light.
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-sterlized after opening.

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

No additional information available

8.2. Exposure controls

Appropriate engineering controls	:	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
Personal protective equipment	:	Wear fire/flame resistant/retardant clothing.
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.
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. The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it.
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).
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).
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	:	No data available
pH	:	7,2 - 7,4
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Non flammable
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	highly soluble in water. Water: complete
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

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 12 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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified. Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified
Potential adverse human health effects and symptoms	:	Based on available data, the classification criteria are not met.
Other information	:	Human Albumin Solution: 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. Route of exposure: Under normal conditions there is no exposure to the product.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

VitriFreeze – Freezing 2	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

VitriFreeze – Freezing 2	
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. 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

Not regulated for transport

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

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

Contains no REACH candidate substance

15.1.2. National regulations

No additional information available

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.

Full text of H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4

H302	Harmful if swallowed

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 : **VitriThaw - Thawing 1**

Product code : VT1005

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 : Cell culture medium for warming human embryos following vitrification

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro N.V.
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

No additional information available

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 (EC no) 231-791-2	70 - 90	Not classified
Sucrose	(CAS No) 57-50-1 (EC no) 200-334-9	10 - 20	Not classified
Human serum albumin	(CAS No) 70024-90-7	1 - 5	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC no) 231-598-3	0,1 - 1	Not classified
Disodium Phosphate Dihydrate	(CAS No) 10028-24-7	< 0,1	Not classified
Potassium Chloride	(CAS No) 7447-40-7 (EC no) 231-211-8	< 0,1	Not classified
Potassium Dihydrogen Phosphate	(CAS No) 7778-77-0 (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 : Assure fresh air breathing. 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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : 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 : Keep container closed when not in use. Keep only in the original container away from direct (sun)light. 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-sterlized after opening.

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

No additional information available

8.2. Exposure controls

Appropriate engineering controls:	:	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
Personal protective equipment:	:	Wear fire/flame resistant/retardant clothing.
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.
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. The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it.
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).
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).
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	:	No data available
pH	:	7,2 - 7,4
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Non flammable
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	highly soluble in water. Water: complete
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

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 12 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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified. Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified
Potential adverse human health effects and symptoms	:	Based on available data, the classification criteria are not met.
Other information	:	Human Albumin Solution: 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. Route of exposure: Under normal conditions there is no exposure to the product.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

VitriThaw – Thawing 1	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

VitriThaw – Thawing 1	
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. 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

Not regulated for transport

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

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

Contains no REACH candidate substance

15.1.2. National regulations

No additional information available

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 : **VitriThaw - Thawing 2**
Product code : VT2001

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 : Cell culture medium for warming human embryos following vitrification

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro N.V.
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

No additional information available

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 (EC no) 231-791-2	90 - 99	Not classified
Sucrose	(CAS No) 57-50-1 (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 (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 (EC no) 231-211-8	< 0,1	Not classified
Potassium Dihydrogen Phosphate	(CAS No) 7778-77-0 (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 : Assure fresh air breathing. 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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : 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 : Keep container closed when not in use. Keep only in the original container away from direct (sun)light. 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-sterlized after opening.

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

No additional information available

8.2. Exposure controls

Appropriate engineering controls:	:	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
Personal protective equipment:	:	Wear fire/flame resistant/retardant clothing.
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.
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. The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it.
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).
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).
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	:	No data available
pH	:	7,2 - 7,4
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Non flammable
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	highly soluble in water. Water: complete
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

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 12 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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified. Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified
Potential adverse human health effects and symptoms	:	Based on available data, the classification criteria are not met.
Other information	:	Human Albumin Solution: 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. Route of exposure: Under normal conditions there is no exposure to the product.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

VitriThaw – Thawing 2	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

VitriThaw – Thawing 2	
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. 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

Not regulated for transport

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

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

Contains no REACH candidate substance

15.1.2. National regulations

No additional information available

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 : **VitriThaw - Thawing 3**
Product code : VT3001

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 : Cell culture medium for warming human embryos following vitrification

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro N.V.
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

No additional information available

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 (EC no) 231-791-2	90 - 99	Not classified
Sucrose	(CAS No) 57-50-1 (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 (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 (EC no) 231-211-8	< 0,1	Not classified
Potassium Dihydrogen Phosphate	(CAS No) 7778-77-0 (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 : Assure fresh air breathing. 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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : 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 : Keep container closed when not in use. Keep only in the original container away from direct (sun)light. 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-sterlized after opening.

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

No additional information available

8.2. Exposure controls

Appropriate engineering controls	:	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
Personal protective equipment	:	Wear fire/flame resistant/retardant clothing.
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.
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. The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it.
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).
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).
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	:	No data available
pH	:	7,2 - 7,4
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Non flammable
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	highly soluble in water. Water: complete
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

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 12 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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified. Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified
Potential adverse human health effects and symptoms	:	Based on available data, the classification criteria are not met.
Other information	:	Human Albumin Solution: 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. Route of exposure: Under normal conditions there is no exposure to the product.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

VitriThaw – Thawing 3	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

VitriThaw – Thawing 3	
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. 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

Not regulated for transport

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

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

Contains no REACH candidate substance

15.1.2. National regulations

No additional information available

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 : **VitriThaw – Thawing 4**

Product code : VT4001

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 : Cell culture medium for the warming of human embryos following vitrification

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro N.V.
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

No additional information available

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 (EC no) 231-791-2	90 - 99	Not classified
Human serum albumin	(CAS No) 70024-90-7	1 - 5	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (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 (EC no) 231-211-8	< 0,1	Not classified
Potassium Dihydrogen Phosphate	(CAS No) 7778-77-0 (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 : Assure fresh air breathing. 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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : 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 : Keep container closed when not in use.
Keep only in the original container away from direct (sun)light.
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-sterlized after opening.

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

No additional information available

8.2. Exposure controls

Appropriate engineering controls:	:	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
Personal protective equipment:	:	Wear fire/flame resistant/retardant clothing.
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.
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. The selected protective gloves have to meet the specifications of EU-directive 89/686/EEC and the standard EN374 derived from it.
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).
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).
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	:	No data available
pH	:	7,2 - 7,4
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Non flammable
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	highly soluble in water. Water: complete
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

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 12 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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified. Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified
Potential adverse human health effects and symptoms	:	Based on available data, the classification criteria are not met.
Other information	:	Human Albumin Solution: 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. Route of exposure: Under normal conditions there is no exposure to the product.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

VitriThaw – Thawing 4	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

VitriThaw – Thawing 4	
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. 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

Not regulated for transport

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

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

Contains no REACH candidate substance

15.1.2. National regulations

No additional information available

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