

Safety Data Sheet according to Regulation (EC) No. 453/2010

Revision date: 07/12/2017 Version: D.1

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze

Freezing 2: page 11>15

VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30

// VitriThaw Thawing 4: page 31>35

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

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.

Uses advised against

No additional information available

Details of the supplier of the safety data sheet

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

Emergency telephone number

Emergency number : +3250791805

SECTION 2: Hazards identification

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

Label elements

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

No labelling applicable

Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

Substance

Not applicable

Mixture 3.2.

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.

ID: FP09 I46 R02 07/12/2017 EN (English) 1/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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.

07/12/2017 EN (English) ID: FP09 I46 R02 2/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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.

<u>Personal protective equipment</u>: 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 : No data available Freezing point **Boiling point** No data available No data available Flash point Auto-ignition temperature : No data available No data available Decomposition temperature Flammability (solid, gas) Non flammable No data available Vapour pressure 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.

07/12/2017 EN (English) ID: FP09 I46 R02 3/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

Possibility of hazardous reactions

Not established.

10.4. **Conditions to avoid**

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

Incompatible materials

Strong acids. Strong bases.

Hazardous decomposition products 10.6.

Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

Information on toxicological effects 11.1.

Acute toxicity : Not classified.

Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.

Skin corrosion/irritation : Not classified : Not classified Serious eye damage/irritation Respiratory or skin sensitisation : Not classified : Not classified Germ cell mutagenicity Carcinogenicity Not classified Reproductive toxicity : Not classified Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated : Not classified

exposure)

: Not classified Aspiration hazard

Potential adverse human health effects and

symptoms

Other information

: Based on available data, the classification criteria are not met.

: 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

Toxicity

No additional information available

Persistence and degradability

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

12.3. **Bioaccumulative potential**

VitriFreeze - Pre-incubation medium

Bioaccumulative potential Not established.

Mobility in soil

No additional information available

Results of PBT and vPvB assessment

No additional information available

Other adverse effects 12.6

Avoid release to the environment

SECTION 13: Disposal considerations

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

ID: FP09 I46 R02 07/12/2017 EN (English) 4/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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

Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable : Not applicable Transport hazard class(es) (IMDG) 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 : Not applicable Packing group (RID)

Environmental hazards

: No Dangerous for the environment Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Not applicable

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. **EU-Regulations**

No REACH Annex XVII restrictions

Contains no REACH candidate substance

National regulations

No additional information available

Chemical safety assessment 15.2.

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

ID: FP09 I46 R02 07/12/2017 EN (English) 5/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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

07/12/2017 EN (English) ID: FP09 I46 R02 6/36

[:] 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.

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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.

: Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct (sun)light.

Storage temperature : 2 - 8 °C

7.3. Specific end use(s)

Incompatible products

See instructions for use delivered with the device.

07/12/2017 EN (English) ID: FP09 I46 R02 7/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

gineering controls
 Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
 ctive equipment
 Wear fire/flame resistant/retardant clothing.

Personal protective equipment

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.

Tabolatory practices. Wash and dry hand

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

: No data available Relative evaporation rate (butylacetate=1) : No data available Melting point No data available Freezing point : No data available **Boiling point** Flash point : No data available : No data available Auto-ignition temperature 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 : No data available

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.

07/12/2017 EN (English) ID: FP09 I46 R02 8/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

Possibility of hazardous reactions

Not established.

10.4. **Conditions to avoid**

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

Incompatible materials

Strong acids. Strong bases.

Hazardous decomposition products 10.6.

Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

Information on toxicological effects 11.1.

Acute toxicity : Not classified.

Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.

Skin corrosion/irritation : Not classified : Not classified Serious eye damage/irritation Respiratory or skin sensitisation : Not classified : Not classified Germ cell mutagenicity Carcinogenicity Not classified Reproductive toxicity : Not classified Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated : Not classified

exposure)

Aspiration hazard : Not classified

Potential adverse human health effects and

symptoms

Other information

: Based on available data, the classification criteria are not met.

: 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

Toxicity

No additional information available

Persistence and degradability

VitriFreeze – Freezing 1	
Persistence and degradability	Not established.

12.3. **Bioaccumulative potential**

VitriFreeze - Freezing 1

Bioaccumulative potential Not established.

Mobility in soil

No additional information available

Results of PBT and vPvB assessment

No additional information available

Other adverse effects 12.6

Avoid release to the environment

SECTION 13: Disposal considerations

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

ID: FP09 I46 R02 07/12/2017 EN (English) 9/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

14.1	IIN	num	hor
14.	יוט	Hulli	Dei

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:

Tull text of Traile Eot i prilases.	
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

07/12/2017 EN (English) ID: FP09 I46 R02 10/36



Safety Data Sheet according to Regulation (EC) No. 453/2010

Revision date: 07/12/2017 Version: D.1

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze

Freezing 2: page 11>15

VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30

// VitriThaw Thawing 4: page 31>35

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

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.

Uses advised against

No additional information available

Details of the supplier of the safety data sheet

FertiPro N.V. Industriepark Noord 32 8730 Beernem Belgium

info@fertipro.com

Emergency telephone number

Emergency number : +3250791805

SECTION 2: Hazards identification

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

Label elements

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

EUH phrases : EUH210 - Safety data sheet available on request

Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

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

ID: FP09 I46 R02 07/12/2017 EN (English) 11/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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

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.

Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media

: Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media

: Do not use a heavy water stream.

Special hazards arising from the substance or mixture

No additional information available

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

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.

Methods and material for containment and cleaning up 6.3.

: Collect spillage. Store away from other materials. Methods for cleaning up

Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

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.

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.

ID: FP09 I46 R02 07/12/2017 EN (English) 12/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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

Skin protection:

Appropriate engineering controls

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

Personal protective equipment

: 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.

Wear fire/flame resistant/retardant clothing.

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 No data available Freezing point 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

07/12/2017 EN (English) ID: FP09 I46 R02 13/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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.

Possibility of hazardous reactions 10.3.

Not established.

Conditions to avoid 10.4.

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

Incompatible materials

Strong acids. Strong bases.

10.6. **Hazardous decomposition products**

Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

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 : Not classified

exposure)

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

Results of PBT and vPvB assessment

No additional information available

Other adverse effects

Avoid release to the environment

ID: FP09 I46 R02 07/12/2017 EN (English) 14/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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
Full text of H- and EUH-phrases:

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

07/12/2017 EN (English) ID: FP09 I46 R02 15/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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

07/12/2017 ID: FP09 I46 R02 16/36 EN (English)



Safety Data Sheet according to Regulation (EC) No. 453/2010

Revision date: 07/12/2017 Version: D.1

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze

Freezing 2: page 11>15

VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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

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

Details of the supplier of the safety data sheet

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

Emergency telephone number 1.4.

Emergency number : +3250791805

SECTION 2: Hazards identification

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

Label elements

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

No labelling applicable

Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

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

ID: FP09 I46 R02 07/12/2017 EN (English) 17/36

[:] 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.

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anythi

: 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.

07/12/2017 EN (English) ID: FP09 I46 R02 18/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

SECTION 8: Exposure controls/personal protection

8.1. **Control parameters**

No additional information available

Exposure controls

: Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure. Appropriate engineering controls:

Personal protective equipment: Wear fire/flame resistant/retardant clothing.

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The Skin protection:

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.

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). Eye/Face 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).

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

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

: Liquid Physical state

Colour : Clear, colorless liquid.

Odour Odourless.

Odour threshold No data available

pΗ : 7.2 - 7.4

Relative evaporation rate (butylacetate=1) : No data available No data available Melting point Freezing point No data available **Boiling point** : No data available Flash point : No data available No data available Auto-ignition temperature 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 : highly soluble in water. Solubility Water: complete Log Pow : No data available Viscosity, kinematic : No data available Viscosity, dynamic No data available

No data available Explosive properties Oxidising properties : No data available Explosive limits : No data available

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.

ID: FP09 I46 R02 07/12/2017 EN (English) 19/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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 : Not classified Reproductive toxicity Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated : Not classified

exposure)

Aspiration hazard : Not classified

Potential adverse human health effects and

symptoms

Other information

: Based on available data, the classification criteria are not met.

: 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

07/12/2017 EN (English) ID: FP09 I46 R02 20/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

UN number

Not regulated for transport

UN proper shipping name

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

Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable : Not applicable Transport hazard class(es) (IMDG) 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 : Not applicable Packing group (RID)

Environmental hazards

: No Dangerous for the environment Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Not applicable

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. **EU-Regulations**

No REACH Annex XVII restrictions

Contains no REACH candidate substance

National regulations

No additional information available

Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE Data sources

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

ID: FP09 I46 R02 07/12/2017 EN (English) 21/36



Safety Data Sheet according to Regulation (EC) No. 453/2010

Revision date: 07/12/2017 Version: D.1

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze

Freezing 2: page 11>15

VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30

// VitriThaw Thawing 4: page 31>35

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

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

Details of the supplier of the safety data sheet

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

Emergency telephone number 1.4.

Emergency number : +3250791805

SECTION 2: Hazards identification

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

Label elements

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

No labelling applicable

Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

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

ID: FP09 I46 R02 07/12/2017 EN (English) 22/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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.

07/12/2017 EN (English) ID: FP09 I46 R02 23/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

SECTION 8: Exposure controls/personal protection

8.1. **Control parameters**

No additional information available

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.

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

substance at the specific workplace.

Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal Hand protection 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.

Face shield and safety glasses. Use equipment for eye protection tested and approved under Eye/Face protection

appropriate government standards such as NIOSH (US) or EN 166 (EU).

Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate Respiratory protection 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

Information on basic physical and chemical properties

Physical state : Liquid

Colour Clear, colorless liquid.

Odour Odourless.

Odour threshold : No data available

7,2 - 7,4

Relative evaporation rate (butylacetate=1) : No data available Melting point : No data available : No data available Freezing point **Boiling point** No data available No data available Flash point Auto-ignition temperature : No data available : No data available Decomposition temperature Flammability (solid, gas) Non flammable No data available Vapour pressure 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 No data available Viscosity, dynamic Explosive properties No data available Oxidising properties No data available : No data available Explosive limits

Other information

No additional information available

SECTION 10: Stability and reactivity

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.

ID: FP09 I46 R02 07/12/2017 EN (English) 24/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

Possibility of hazardous reactions

Not established.

10.4. **Conditions to avoid**

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

Incompatible materials

Strong acids. Strong bases.

Hazardous decomposition products 10.6.

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 Not classified Reproductive toxicity Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated : Not classified

exposure)

: Not classified

Potential adverse human health effects and

symptoms

: Based on available data, the classification criteria are not met.

Other information

Aspiration hazard

: 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

Persistence and degradability 12.2.

VitriThaw – Thawing 2	
Persistence and degradability	Not established.

12.3. **Bioaccumulative potential**

VitriThaw – Thawing 2		
Bioaccumulative notential	Not established	

Mobility in soil 12.4.

No additional information available

Results of PBT and vPvB assessment

No additional information available

Other adverse effects

Avoid release to the environment

SECTION 13: Disposal considerations

Waste treatment methods

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

: Avoid release to the environment. Ecology - waste materials

SECTION 14: Transport information

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

ID: FP09 I46 R02 07/12/2017 EN (English) 25/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

UN number

Not regulated for transport

UN proper shipping name

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

Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable : Not applicable Transport hazard class(es) (IMDG) 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 : Not applicable Packing group (RID)

Environmental hazards

: No Dangerous for the environment Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Not applicable

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. **EU-Regulations**

No REACH Annex XVII restrictions

Contains no REACH candidate substance

National regulations

No additional information available

Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE Data sources

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

ID: FP09 I46 R02 07/12/2017 EN (English) 26/36



Safety Data Sheet according to Regulation (EC) No. 453/2010

Revision date: 07/12/2017 Version: D.1

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze

Freezing 2: page 11>15

VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30

// VitriThaw Thawing 4: page 31>35

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

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

Details of the supplier of the safety data sheet

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

Emergency telephone number 1.4.

Emergency number : +3250791805

SECTION 2: Hazards identification

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

Label elements

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

No labelling applicable

Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

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.

ID: FP09 I46 R02 07/12/2017 EN (English) 27/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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.

07/12/2017 EN (English) ID: FP09 I46 R02 28/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

SECTION 8: Exposure controls/personal protection

8.1. **Control parameters**

No additional information available

Exposure controls

: Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure. Appropriate engineering controls

Personal protective equipment Wear fire/flame resistant/retardant clothing.

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The Skin protection

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.

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). Eye/Face 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).

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

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state : Liauid

Colour : Clear, colorless liquid.

Odour Odourless.

Odour threshold No data available

pΗ : 7.2 - 7.4

Relative evaporation rate (butylacetate=1) : No data available Melting point : No data available Freezing point No data available : No data available **Boiling point** Flash point : No data available No data available Auto-ignition temperature 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

: highly soluble in water. Solubility 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

Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

Chemical stability

Stable after transport (max. 5 days) at elevated temperature (≤ 37°C). Stable for 12 months from date of manufacture.

ID: FP09 I46 R02 07/12/2017 FN (Fnglish) 29/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

Possibility of hazardous reactions

Not established.

10.4. **Conditions to avoid**

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

Incompatible materials

Strong acids. Strong bases.

Hazardous decomposition products 10.6.

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 : Not classified Reproductive toxicity Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated : Not classified

exposure) 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.

Mobility in soil

No additional information available

Results of PBT and vPvB assessment

No additional information available

Other adverse effects

Avoid release to the environment

SECTION 13: Disposal considerations

Waste treatment methods

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

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

ID: FP09 I46 R02 07/12/2017 EN (English) 30/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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

07/12/2017 EN (English) ID: FP09 I46 R02 31/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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.

07/12/2017 EN (English) ID: FP09 I46 R02 32/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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.

: Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct (sun)light.

Storage temperature : 2 - 8 °C

7.3. Specific end use(s)

Incompatible products

See instructions for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

07/12/2017 EN (English) ID: FP09 I46 R02 33/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15
VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

8.2. Exposure controls

Appropriate engineering controls: : Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

<u>Personal protective equipment:</u> : 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 No data available Melting point Freezing point No data available No data available **Boiling point** Flash point : No data available No data available Auto-ignition temperature No data available Decomposition temperature · Non flammable Flammability (solid, gas) : No data available Vapour pressure Relative vapour density at 20 °C : No data available Relative density No data available highly soluble in water. Solubility

nignly soluble in water.Water: complete No data available

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.

07/12/2017 EN (English) ID: FP09 I46 R02 34/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

Conditions to avoid

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

Incompatible materials 10.5.

Strong acids. Strong bases.

Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

Information on toxicological effects 11.1.

Acute toxicity : Not classified. Extensive data from Mouse Embryo Assays have demonstrated that the medium

is not toxic.

: Not classified Skin corrosion/irritation Serious eye damage/irritation : Not classified Respiratory or skin sensitisation : Not classified Germ cell mutagenicity : Not classified : Not classified Carcinogenicity Reproductive toxicity : Not classified Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated : Not classified

exposure)

Aspiration hazard : Not classified

Potential adverse human health effects and

symptoms

Other information

: Based on available data, the classification criteria are not met.

: 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

Toxicity 12.1.

No additional information available

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

Results of PBT and vPvB assessment

No additional information available

Other adverse effects

Avoid release to the environment

SECTION 13: Disposal considerations

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

UN number

Not regulated for transport

ID: FP09 I46 R02 07/12/2017 EN (English) 35/36

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Safety data: VitriFreeze Pre-incubation: page 1>5 // VitriFreeze Freezing 1: page 6>10 // VitriFreeze Freezing 2: page 11>15 VitriThaw Thawing 1: page 16>20 // VitriThaw Thawing 2: page 21>25 // VitriThaw Thawing 3: page 26>30 // VitriThaw Thawing 4: page 31>35

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

Transport hazard class(es)

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

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**

: No Dangerous for the environment Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Not applicable

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. **EU-Regulations**

No REACH Annex XVII restrictions

Contains no REACH candidate substance

National regulations 15.1.2.

No additional information available

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

ID: FP09 I46 R02 07/12/2017 EN (English) 36/36