

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

### 1.1 Product identifier

Product form : Mixture  
Product name : GentleVit Freeze Kit  
(GentleVit Pre-Vitrification Medium, Gentle Vit Freeze Medium 1-5)  
Product code : 4 GF1001

### 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 : Universal cell culture media for the vitrification of human oocytes and embryos.

#### 1.2.2. Uses advised against

No additional information available.

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

Gynemed GmbH & Co. KG  
Lübecker Straße 9  
D-23738 Lensahn  
Germany  
info@gynemed.de

### 1.4 Emergency telephone number

Emergency number : +49 (0)4363 90 32 90

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]  
Not classified

Classification according to Directive 67/548/EEC or 1999/45/EC  
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

#### GentleVit Pre-Vitrification Medium

| Name                       | Product identifier                      | %       | Classification according to Directive 67/548/EEC | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|----------------------------|---|---------|--|---|
| Ultrapure water            | (CAS No) 7732-18-5<br>(EC No) 231-791-2 | 90 - 99 | Not classified                                   | Not classified  |
| Human Serum Albumin        | (CAS No) 70024-90-7                     | 2       | Not classified                                   | Not classified  |
| Sodium Chloride            | (CAS No) 7647-14-5<br>(EC No) 231-598-3 | 0.1 - 1 | Not classified                                   | Not classified  |
| HEPES                      | (CAS No) 7365-45-9<br>(EC No) 230-907-9 | 0.1 - 1 | Not classified                                   | Not classified  |
| Sodium lactate             | (CAS No) 867-56-1<br>(EC No) 212-762-3  | 0.1 - 1 | Not classified                                   | Not classified  |
| D- (+)- Glucose            | (CAS No) 50-99-7<br>(EC No) 200-075-1   | < 0.1   | Not classified                                   | Not classified  |
| Sodium Hydrogen Carbonate  | (CAS No) 144-55-8<br>(EC No) 205-633-8  | < 0.1   | Not classified                                   | Not classified  |
| Sodium Pyruvate            | (CAS No) 113-24-6<br>(EC No) 204-024-4  | < 0.1   | Not classified                                   | Not classified  |
| Potassium Chloride         | (CAS No) 7447-40-7<br>(EC No) 231-211-8 | < 0.1   | Not classified                                   | Not classified  |
| Calcium Chloride Dihydrate | (CAS No)10035-04-8                      | < 0.1   | Xi; R36  | Eye Irrit. 2, H319  |

| Name                                   | Product identifier                      | %     | Classification according to Directive 67/548/EEC | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|--|---|-------|--|---|
| <b>Potassium Dihydrogen Phosphate</b>  | (CAS No) 7778-77-0<br>(EC No) 231-913-4 | < 0.1 | Not classified                                   | Not classified  |
| <b>Magnesium Sulphate Heptahydrate</b> | (CAS No) 10034-99-8                     | < 0.1 | Not classified                                   | Not classified  |

Full text of R- and 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. |
|----------|---|--|

**GentleVit Freeze Medium 1**

| Name                                   | Product identifier   | %       | Classification according to Directive 67/548/EEC | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|--|--|---------|--|---|
| <b>Ultrapure water</b>                 | (CAS No) 7732-18-5<br>(EC No) 231-791-2                              | 90 - 99 | Not classified                                   | Not classified  |
| <b>Dimethyl sulphoxide (DMSO)</b>      | (CAS No) 67-68-5   | 1.25    | Not classified                                   | Not classified  |
| <b>Ethylene Glycol</b>                 | (CAS No) 107-21-1<br>(EC No) 203-473-3<br>(EC Index No) 603-027-00-1 | 1.25    | Xn; R22  | Acute Tox. 4 (Oral), H302                                       |
| <b>Human Serum Albumin</b>             | (CAS No) 70024-90-7  | 2       | Not classified                                   | Not classified  |
| <b>Sodium Chloride</b>                 | (CAS No) 7647-14-5<br>(EC No) 231-598-3                              | 0.1 - 1 | Not classified                                   | Not classified  |
| <b>HEPES</b>                           | (CAS No) 7365-45-9<br>(EC No) 230-907-9                              | 0.1 - 1 | Not classified                                   | Not classified  |
| <b>Sodium lactate</b>                  | (CAS No) 867-56-1<br>(EC No) 212-762-3                               | 0.1 - 1 | Not classified                                   | Not classified  |
| <b>D- (+)- Glucose</b>                 | (CAS No) 50-99-7<br>(EC No) 200-075-1                                | < 0.1   | Not classified                                   | Not classified  |
| <b>Sodium Hydrogen Carbonate</b>       | (CAS No) 144-55-8<br>(EC No) 205-633-8                               | < 0.1   | Not classified                                   | Not classified  |
| <b>Sodium Pyruvate</b>                 | (CAS No) 113-24-6<br>(EC No) 204-024-4                               | < 0.1   | Not classified                                   | Not classified  |
| <b>Potassium Chloride</b>              | (CAS No) 7447-40-7<br>(EC No) 231-211-8                              | < 0.1   | Not classified                                   | Not classified  |
| <b>Calcium Chloride Dihydrate</b>      | (CAS No) 10035-04-8  | < 0.1   | Xi; R36  | Eye Irrit. 2, H319  |
| <b>Potassium Dihydrogen Phosphate</b>  | (CAS No) 7778-77-0<br>(EC No) 231-913-4                              | < 0.1   | Not classified                                   | Not classified  |
| <b>Magnesium Sulphate Heptahydrate</b> | (CAS No) 10034-99-8  | < 0.1   | Not classified                                   | Not classified  |

Full text of R- and 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. |
|----------|---|--|

**GentleVit Freeze Medium 2**

| Name                              | Product identifier   | %       | Classification according to Directive 67/548/EEC | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-----------------------------------|--|---------|--|---|
| <b>Ultrapure water</b>            | (CAS No) 7732-18-5<br>(EC No) 231-791-2                              | 90 - 99 | Not classified                                   | Not classified  |
| <b>Dimethyl sulphoxide (DMSO)</b> | (CAS No) 67-68-5   | 2.5     | Not classified                                   | Not classified  |
| <b>Ethylene Glycol</b>            | (CAS No) 107-21-1<br>(EC No) 203-473-3<br>(EC Index No) 603-027-00-1 | 2.5     | Xn; R22  | Acute Tox. 4 (Oral), H302                                       |
| <b>Human Serum Albumin</b>        | (CAS No) 70024-90-7  | 2       | Not classified                                   | Not classified  |
| <b>Sodium Chloride</b>            | (CAS No) 7647-14-5<br>(EC No) 231-598-3                              | 0.1 - 1 | Not classified                                   | Not classified  |
| <b>HEPES</b>                      | (CAS No) 7365-45-9<br>(EC No) 230-907-9                              | 0.1 - 1 | Not classified                                   | Not classified  |
| <b>Sodium lactate</b>             | (CAS No) 867-56-1<br>(EC No) 212-762-3                               | 0.1 - 1 | Not classified                                   | Not classified  |
| <b>D- (+)- Glucose</b>            | (CAS No) 50-99-7<br>(EC No) 200-075-1                                | < 0.1   | Not classified                                   | Not classified  |

| Name  | Product identifier                      | %  | Classification according to Directive 67/548/EEC | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---|--|--|---|
| <b>Sodium Hydrogen Carbonate</b>              | (CAS No) 144-55-8<br>(EC No) 205-633-8  | < 0.1  | Not classified                                   | Not classified  |
| <b>Sodium Pyruvate</b>                        | (CAS No) 113-24-6<br>(EC No) 204-024-4  | < 0.1  | Not classified                                   | Not classified  |
| <b>Potassium Chloride</b>                     | (CAS No) 7447-40-7<br>(EC No) 231-211-8 | < 0.1  | Not classified                                   | Not classified  |
| <b>Calcium Chloride Dihydrate</b>             | (CAS No)10035-04-8                      | < 0.1  | Xi; R36  | Eye Irrit. 2, H319  |
| <b>Potassium Dihydrogen Phosphate</b>         | (CAS No) 7778-77-0<br>(EC No) 231-913-4 | < 0.1  | Not classified                                   | Not classified  |
| <b>Magnesium Sulphate Heptahydrate</b>        | (CAS No) 10034-99-8                     | < 0.1  | Not classified                                   | Not classified  |
| Full text of R- and 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. |  |   |

#### GentleVit Freeze Medium 3

| Name  | Product identifier   | %  | Classification according to Directive 67/548/EEC | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|--|--|--|---|
| <b>Ultrapure water</b>                        | (CAS No) 7732-18-5<br>(EC No) 231-791-2                              | 80 - 89  | Not classified                                   | Not classified  |
| <b>Dimethyl sulphoxide (DMSO)</b>             | (CAS No) 67-68-5   | 5  | Not classified                                   | Not classified  |
| <b>Ethylene Glycol</b>                        | (CAS No) 107-21-1<br>(EC No) 203-473-3<br>(EC Index No) 603-027-00-1 | 5  | Xn; R22  | Acute Tox. 4 (Oral), H302                                       |
| <b>Human Serum Albumin</b>                    | (CAS No) 70024-90-7  | 1.8  | Not classified                                   | Not classified  |
| <b>Sodium Chloride</b>                        | (CAS No) 7647-14-5<br>(EC No) 231-598-3                              | 0.1 - 1  | Not classified                                   | Not classified  |
| <b>HEPES</b>                                  | (CAS No) 7365-45-9<br>(EC No) 230-907-9                              | 0.1 - 1  | Not classified                                   | Not classified  |
| <b>Sodium lactate</b>                         | (CAS No) 867-56-1<br>(EC No) 212-762-3                               | 0.1 - 1  | Not classified                                   | Not classified  |
| <b>D- (+)- Glucose</b>                        | (CAS No) 50-99-7<br>(EC No) 200-075-1                                | < 0.1  | Not classified                                   | Not classified  |
| <b>Sodium Hydrogen Carbonate</b>              | (CAS No) 144-55-8<br>(EC No) 205-633-8                               | < 0.1  | Not classified                                   | Not classified  |
| <b>Sodium Pyruvate</b>                        | (CAS No) 113-24-6<br>(EC No) 204-024-4                               | < 0.1  | Not classified                                   | Not classified  |
| <b>Potassium Chloride</b>                     | (CAS No) 7447-40-7<br>(EC No) 231-211-8                              | < 0.1  | Not classified                                   | Not classified  |
| <b>Calcium Chloride Dihydrate</b>             | (CAS No)10035-04-8   | < 0.1  | Xi; R36  | Eye Irrit. 2, H319  |
| <b>Potassium Dihydrogen Phosphate</b>         | (CAS No) 7778-77-0<br>(EC No) 231-913-4                              | < 0.1  | Not classified                                   | Not classified  |
| <b>Magnesium Sulphate Heptahydrate</b>        | (CAS No) 10034-99-8  | < 0.1  | Not classified                                   | Not classified  |
| Full text of R- and 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. |  |   |

#### GentleVit Freeze Medium 4

| Name                              | Product identifier   | %       | Classification according to Directive 67/548/EEC | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-----------------------------------|--|---------|--|---|
| <b>Ultrapure water</b>            | (CAS No) 7732-18-5<br>(EC No) 231-791-2                              | 70 - 79 | Not classified                                   | Not classified  |
| <b>Dimethyl sulphoxide (DMSO)</b> | (CAS No) 67-68-5   | 10      | Not classified                                   | Not classified  |
| <b>Ethylene Glycol</b>            | (CAS No) 107-21-1<br>(EC No) 203-473-3<br>(EC Index No) 603-027-00-1 | 10      | Xn; R22  | Acute Tox. 4 (Oral), H302                                       |
| <b>Human Serum Albumin</b>        | (CAS No) 70024-90-7  | 1.6     | Not classified                                   | Not classified  |

| Name  | Product identifier                      | %       | Classification according to Directive 67/548/EEC   | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---|---------|--|---|
| Sodium Chloride                               | (CAS No) 7647-14-5<br>(EC No) 231-598-3 | 0.1 - 1 | Not classified   | Not classified  |
| HEPES   | (CAS No) 7365-45-9<br>(EC No) 230-907-9 | 0.1 - 1 | Not classified   | Not classified  |
| Sodium lactate                                | (CAS No) 867-56-1<br>(EC No) 212-762-3  | 0.1 - 1 | Not classified   | Not classified  |
| D- (+)- Glucose                               | (CAS No) 50-99-7<br>(EC No) 200-075-1   | < 0.1   | Not classified   | Not classified  |
| Sodium Hydrogen Carbonate                     | (CAS No) 144-55-8<br>(EC No) 205-633-8  | < 0.1   | Not classified   | Not classified  |
| Sodium Pyruvate                               | (CAS No) 113-24-6<br>(EC No) 204-024-4  | < 0.1   | Not classified   | Not classified  |
| Potassium Chloride                            | (CAS No) 7447-40-7<br>(EC No) 231-211-8 | < 0.1   | Not classified   | Not classified  |
| Calcium Chloride Dihydrate                    | (CAS No)10035-04-8                      | < 0.1   | Xi; R36  | Eye Irrit. 2, H319  |
| Potassium Dihydrogen Phosphate                | (CAS No) 7778-77-0<br>(EC No) 231-913-4 | < 0.1   | Not classified   | Not classified  |
| Magnesium Sulphate Heptahydrate               | (CAS No) 10034-99-8                     | < 0.1   | Not classified   | Not classified  |
| Full text of R- and 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. |   |

#### GentleVit Freeze Medium 5

| Name  | Product identifier   | %       | Classification according to Directive 67/548/EEC   | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|--|---------|--|---|
| Ultrapure water                               | (CAS No) 7732-18-5<br>(EC No) 231-791-2                              | 30 – 50 | Not classified   | Not classified  |
| Sucrose                                       | (CAS No) 57-50-1<br>(EC No) 200-334-9                                | 20 - 30 | Not classified   | Not classified  |
| Dimethyl sulphoxide (DMSO)                    | (CAS No) 67-68-5   | 20      | Not classified   | Not classified  |
| Ethylene Glycol                               | (CAS No) 107-21-1<br>(EC No) 203-473-3<br>(EC Index No) 603-027-00-1 | 20      | Xn; R22  | Acute Tox. 4 (Oral), H302                                       |
| Ficoll  | (CAS No) 26873-85-8  | 0.1 - 1 | Not classified   | Not classified  |
| Human Serum Albumin                           | (CAS No) 70024-90-7  | 1       | Not classified   | Not classified  |
| Sodium Chloride                               | (CAS No) 7647-14-5<br>(EC No) 231-598-3                              | 0.1 - 1 | Not classified   | Not classified  |
| HEPES   | (CAS No) 7365-45-9<br>(EC No) 230-907-9                              | 0.1 - 1 | Not classified   | Not classified  |
| Sodium lactate                                | (CAS No) 867-56-1<br>(EC No) 212-762-3                               | < 0.1   | Not classified   | Not classified  |
| D- (+)- Glucose                               | (CAS No) 50-99-7<br>(EC No) 200-075-1                                | < 0.1   | Not classified   | Not classified  |
| Sodium Hydrogen Carbonate                     | (CAS No) 144-55-8<br>(EC No) 205-633-8                               | < 0.1   | Not classified   | Not classified  |
| Sodium Pyruvate                               | (CAS No) 113-24-6<br>(EC No) 204-024-4                               | < 0.1   | Not classified   | Not classified  |
| Potassium Chloride                            | (CAS No) 7447-40-7<br>(EC No) 231-211-8                              | < 0.1   | Not classified   | Not classified  |
| Calcium Chloride Dihydrate                    | (CAS No)10035-04-8   | < 0.1   | Xi; R36  | Eye Irrit. 2, H319  |
| Potassium Dihydrogen Phosphate                | (CAS No) 7778-77-0<br>(EC No) 231-913-4                              | < 0.1   | Not classified   | Not classified  |
| Magnesium Sulphate Heptahydrate               | (CAS No) 10034-99-8  | < 0.1   | Not classified   | Not classified  |
| Full text of R- and H-phrases: see section 16 |  |         |  |   |
| Comments                                      |  | :       | The media do not contain any raw materials of direct animal-origin or materials that have been produced using animal-origin components. Components have not been in contact with material of animal origin during processing and therefore pose no TSE risk. |   |

#### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

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

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

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

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

No additional information available.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

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

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

No additional information available.

#### 5.3 Advice for firefighters

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

### SECTION 6: Accidental release measures

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

##### 6.1.1 For non-emergency personnel

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

##### 6.1.2 For emergency responders

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

#### 6.2 Environmental precautions

Prevent entry to sewers and public waters.

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

|                         |   |                   |
|-------------------------|---|-------------------|
| Methods for cleaning up | : | Collect spillage. |
|-------------------------|---|-------------------|

#### 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.<br>Keep only in the original container away from direct (sun)light.<br>Do not freeze.<br>Do not use after expiry date.<br>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.<br>Content cannot be resterilized 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 instruction for use delivered with the device.

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

No additional information available.

#### 8.2 Exposure controls

|                               |   |                                 |
|-------------------------------|---|---------------------------------|
| Personal protective equipment | : | Avoid all unnecessary exposure. |
| Hand protection               | : | Wear protective gloves.         |

Eye protection : Chemical goggles or safety glasses.  
 Respiratory protection : Wear appropriate mask.  
 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 : 7.20 – 7.50  
 Relative evaporation rate (butylacetate=1) : No data available  
 Melting point : No data available  
 Freezing point : No data available  
 Boiling point : No data available  
 Flash point : No data available  
 Auto-ignition temperature : No data available  
 Decomposition temperature : No data available  
 Flammability (solid, gas) : Non flammable  
 Vapour pressure : No data available  
 Relative vapour density at 20°C : No data available  
 Relativ density : No data available  
 Solubility : 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 ( $\leq 37^{\circ}\text{C}$ ). Stable for 12 month from date of manufacture.

### 10.3 Possibility of hazardous reactions

Not established.

### 10.4 Conditions to avoid

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

### 10.5 Incompatible materials

Strong acids. Strong bases.

### 10.6 Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Acute toxicity : Not classified.  
 Extensive data from Mouse Embryo Assay have demonstrated that the medium is not toxic.  
 Skin corrosion/irritation : Not classified  
 Serious eye damage/irritation : Not classified  
 Respiratory or skin sensitisation : Not classified  
 Germ cell mutagenicity : Not classified  
 Carcinogenicity : Not classified  
 Reproductive toxicity : Not classified  
 Specific target organ toxicity (single exposure) : Not classified  
 Specific target organ toxicity (repeated exposure) : Not classified  
 Aspiration hazard : Not classified  
 Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.  
 Other information : Human Serum Albumin: The plasma which is the source of the human serum albumin is tested for antibodies to HIV and HCV and non-reactive for HbsAg, HBV RNA, HCV RNA, HIV-1 RNA and syphilis. The albumin agrees with all the requirements set forth by the European and United States health authority regarding safety.

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

#### GentleVit Freeze Medium 1

Persistence and degradability : Not established

### 12.3 Bioaccumulative potential

#### GentleVit Freeze Medium 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 environment

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

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

Ecology – waste materials : Avoid release to the environment.

## SECTION 14: Transport information

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

### 14.1 UN number

Not regulated for transport

### 14.2 UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

Proper Shipping Name (ADN) : Not applicable

Proper Shipping Name (RID) : Not applicable

### 14.3 Transport hazard class(es)

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

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

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

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

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

### 14.4 Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

### 14.5 Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

### 14.6 Special precautions for user

Not applicable

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

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1 EU-Regulations

No REACH Annex XVII restrictions.

Contains no REACH candidate substance.

#### 15.1.2 National regulations

No additional information available.

### 15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

**SECTION 16: Other information**

Data sources REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling 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 R-, H- and EUH-phrases

|                     |   |
|---------------------|---|
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4             |
| Eye Irrit. 2        | Serious eye damage/eye irritation, category 2 |
| H302                | Harmful if swallowed                          |
| H319                | Cause serious eye irritation                  |
| R22                 | Harmful if swallowed                          |
| R36                 | Irritating to eye                             |
| Xi                  | Irritant                                      |
| Xn                  | Harmful                                       |

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.