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

1.1. Product identifier

Product form: Mixture
Product name: FertiCult Flushing medium
FertiCult Flushing with phenol red
FertiCult Flushing with phenol red and gentamicin
FertiCult Flushing medium with gentamicin

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 washing of ova, spermatozoa, human embryos, sperm injection during ICSI, sperm swim-up, embryo transfer, intra-uterine insemination and production of density gradients

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrapure water</td>
<td>(CAS No) 7732-18-5 (EC no) 231-791-2</td>
<td>90 - 99</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>(CAS No) 7647-14-5 (EC no) 231-598-3</td>
<td>0.1 - 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>HEPES</td>
<td>(CAS No) 7365-45-9 (EC no) 230-907-9</td>
<td>0.1 - 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Human Serum Albumin</td>
<td>(CAS No) 70024-90-7</td>
<td>0.1 - 1</td>
<td>Not classified</td>
</tr>
</tbody>
</table>
FertiCult Flushing medium
FertiCult Flushing medium with phenol red
FertiCult Flushing medium with phenol red and gentamicin
FertiCult Flushing medium with gentamicin

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<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Lactate</td>
<td>(CAS No) 867-56-1</td>
<td>0,1 - 1</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>(EC no) 212-792-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose Monohydrate</td>
<td>(CAS No) 14431-43-7</td>
<td>0,1 - 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Hydrogen Carbonate</td>
<td>(CAS No) 144-55-8</td>
<td>0,1 - 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>(EC no) 205-633-8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potassium Chloride</td>
<td>(CAS No) 7447-40-7</td>
<td>&lt; 0,1</td>
<td>Not classified</td>
</tr>
<tr>
<td>(EC no) 231-211-8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium Chloride Dihydrate</td>
<td>(CAS No) 10035-04-8</td>
<td>&lt; 0,1</td>
<td>Eye Irrit. 2, H319</td>
</tr>
<tr>
<td>Sodium Dihydrogen Phosphate Dihydrate</td>
<td>(CAS No) 13472-35-0</td>
<td>&lt; 0,1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Magnesium Sulphate Heptahydrate</td>
<td>(CAS No) 10034-99-8</td>
<td>&lt; 0,1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Pyruvate</td>
<td>(CAS No) 113-24-6</td>
<td>0,1</td>
<td>Not classified</td>
</tr>
<tr>
<td>(EC no) 204-024-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentamicin Sulfate</td>
<td>(n° CAS) 1405-41-0</td>
<td>&lt; 1</td>
<td>Resp. Sens. 1, H317, Skin. Sens. 1, H317, Repr. 1A, H360</td>
</tr>
<tr>
<td>Phoenol Red</td>
<td>(n° CAS) 34487-61-1</td>
<td>&lt; 1</td>
<td>Skin.irrit. 2, H315, Eye irrit. 2, H319, Slot.se 3, H336</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16
Comments: The media do not contain any raw materials of direct animal-origin or materials that have been produced using animal-origin components. Components have not been in contact with material of animal origin during processing and therefore pose no TSE risk

SECTION 4: First aid measures

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

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed
No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media
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.
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FertiCult Flushing medium with gentamicin

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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.
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-sterilized after opening.

Incompatible products : Strong bases. Strong acids.
Storage temperature : For FertiCult Flushing medium (with phenol red): 2 - 25 °C (once opened, 2-8°C.)
For FertiCult Flushing medium (with phenol red) and gentamicin: 2-8°C

7.3. Specific end use(s)
See instructions for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
No additional information available

8.2. Exposure controls
Appropriate engineering controls : Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
Personal protective equipment : Wear fire/flame resistant/retardant clothing.
Skin protection : Complete suit protect 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 : white/yellow or reddish traspant liquid.
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Odour: odourless.
Odour threshold: No data available
pH: 7.3 - 7.9
Relative evaporation rate (butylacetate=1): No data available
Melting point: No data available
Freezing point: No data available
Boiling point: No data available
Flash point: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Flammability (solid, gas): Non flammable
Vapour pressure: No data available
Relative vapour density at 20 °C: No data available
Relative density: No data available
Solubility: highly soluble in water. Water: complete
Log Pow: No data available
Viscosity, kinematic: No data available
Viscosity, dynamic: No data available
Explosive properties: Non explosive
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 18 months from date of manufacture.

10.3. Possibility of hazardous reactions
Not established.

10.4. Conditions to avoid
Direct (sun)light; Extremely high or low temperatures.

10.5. Incompatible materials
Strong acids. Strong bases.

10.6. Hazardous decomposition products
Carbon monoxide; Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute toxicity: Not classified
Extensive data on Mouse Embryo Assays have demonstrated that the medium is not toxic
Irritation: Not classified
The medium has been evaluated for its irritating potential by an independent test laboratory using the direct intracutaneous injection test. The medium meets the requirements of the ISO10993-10 guidelines.
Corrosivity: Not classified
Sensitisation: Not classified
The medium has been evaluated for its sensitizing potential by an independent test laboratory using the Kligman maximization test. The medium meets the requirements of the ISO10993-10 guidelines.
Repeated dose toxicity: Not classified
### FertiCult Flushing medium

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### FertiCult Flushing medium with gentamicin

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<table>
<thead>
<tr>
<th>Carcinogenicity</th>
<th>Mutagenicity</th>
<th>Toxicity for reproduction</th>
<th>Potential adverse human health effects and symptoms</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not classified</td>
<td>Not classified</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met.</td>
<td>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: With embryo transfer and intra-uterine insemination, the medium comes into contact with the uterus mucosal membranes.</td>
</tr>
</tbody>
</table>

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general: No known ecological damage caused by this product.

#### 12.2. Persistence and degradability

**FertiCult Flushing Medium- FertiCult Flushing with phenol red- FertiCult Flushing with phenol red and gentamicin- FertiCult Flushing medium with gentamicin**

Persistence and degradability: Not established.

#### 12.3. Bioaccumulative potential

**FertiCult Flushing Medium- FertiCult Flushing with phenol red- FertiCult Flushing with phenol red and gentamicin- FertiCult Flushing medium with gentamicin**

Bioaccumulative potential: Not established.

#### 12.4. Mobility in soil

No additional information available.

#### 12.5. Results of PBT and vPvB assessment

No additional information available.

#### 12.6. Other adverse effects

Avoid release to the environment.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

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

Ecology - waste materials: Avoid release to the environment.

### SECTION 14: Transport information

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

#### 14.1. UN number

Not regulated for transport.

#### 14.2. UN proper shipping name

<table>
<thead>
<tr>
<th>Proper Shipping Name (ADR)</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper Shipping Name (IMDG)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Proper Shipping Name (IATA)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Proper Shipping Name (ADN)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Proper Shipping Name (RID)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

#### 14.3. Transport hazard class(es)

| ADR: Transport hazard class(es) | Not applicable |
| IMDG: Transport hazard class(es) | Not applicable |
| ADN: Transport hazard class(es)  | Not applicable |
| RID: Transport hazard class(es)  | Not applicable |
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14.4. Packing group

<table>
<thead>
<tr>
<th>Packing group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group (ADR)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Packing group (IMDG)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Packing group (IATA)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Packing group (ADN)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Packing group (RID)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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


Other information: None.

Full text of H- and EUH-phrases:

| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| Repr. 1A    | Reproductive toxicity, Category 1A |
| Resp. Sens. 1| Sensitisation — Respiratory, category 1 |
| Skin Irrit. 2| Skin corrosion/irritation, Category 2 |
| Skin Sens. 1| Sensitisation — Skin, category 1 |
| STOT SE 3   | Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation |
| H315        | Causes skin irritation |
| H317        | May cause an allergic skin reaction |
| H319        | Causes serious eye irritation |
| H334        | May cause allergy or asthma symptoms or breathing difficulties if inhaled |
| H335        | May cause respiratory irritation |
| H360        | May damage fertility or the unborn child |

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 therefore be construed as guaranteeing any specific property of the product.